

US3082122 (Prod: Trial Management Associates LLC - ERN - PPDS)

Generated By: KC Joubran

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US3082122

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

[Participant ID](#)

US3082122

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

US3082122

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

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

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

Folder OID	SCRN
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US3082122

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

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

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?

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

If Yes, previous participant number _____

Enrollment Trigger 1

US3082122

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3082122

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Condition	POST MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Condition	BANANA ALLERGY
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 (4)

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Condition	SHELL FISH ALLERGY
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) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

US3082122

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	08:49 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 08:49
Height (xxx.x)	63.5 in
Weight (xxx.x)	117.4 lb
BMI (xxx.x)	20.51306 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 18:15:25

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Date of assessment (dd MMM yyyy) 27 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) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2002

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

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) 19 Feb 2021 18:15:25

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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) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

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

What was the participant's randomization number? 188621

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

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) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	08:49 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 08:49
Temperature (xxx.x)	98.3 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 10:40
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

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) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 27 AUG 2020

What was the treatment time? (00:00-23:59) 10:09 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 10:09

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) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 AUG 2020
Collection time (00:00-23:59)	09:39 (24 HR)
Collection date and time (derived)	27 AUG 2020 09:39

US3082122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:44	27 AUG 2020 09:44
Nasopharyngeal Swab 2	No		

US3082122

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 10:41

PC Open Date & Time

27 AUG 2020 10:29

PC Close Date & Time

27 AUG 2020 12:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp 27 AUG 2020 17:56

PC Open Date & Time 27 AUG 2020 13:54

PC Close Date & Time 28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

28 AUG 2020 18:13

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

29 AUG 2020 18:25

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 17:43

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 18:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

01 SEP 2020 18:31

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °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	02 SEP 2020 18:13
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 8

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

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 9

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

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

27 AUG 2020 10:41

PC Open Date & Time

27 AUG 2020 10:29

PC Close Date & Time

27 AUG 2020 12:59

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

27 AUG 2020 17:58

PC Open Date & Time

27 AUG 2020 13:54

PC Close Date & Time

28 AUG 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

28 AUG 2020 18:13

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

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

29 AUG 2020 18:25

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

30 AUG 2020 17:44

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

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

31 AUG 2020 18:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

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

01 SEP 2020 18:32

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

02 SEP 2020 18:14

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 10:42
PC Open Date & Time	27 AUG 2020 10:29
PC Close Date & Time	27 AUG 2020 12:59

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 17:58
PC Open Date & Time	27 AUG 2020 13:54
PC Close Date & Time	28 AUG 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2106

EAB) (1725)

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 18:14
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

51 of 2106

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 18:26
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

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 ☒

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 17:44
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

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 ☒

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 18:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

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 ☒

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 18:32
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

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 ☒

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 18:15
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3082122

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3082122

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082122

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:14:41

Generated On: 09 Jun 2021 15:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082122

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:14:41

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:14:41

Generated On: 09 Jun 2021 15:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082122

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:14:41

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

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

Visit date (dd MMM yyyy)	29 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

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)	29 SEP 2020
Time of assessment (00:00-23:59)	07:56 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 07:56
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

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)	29 SEP 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:50
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3082122

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3082122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 09:19 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 09:19

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

US3082122

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	09:05 (24 HR)
Collection date and time (derived)	29 SEP 2020 09:05

US3082122

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:08	29 SEP 2020 09:08
Nasopharyngeal Swab 2	No		

US3082122

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 10:41

PC Open Date & Time

29 SEP 2020 09:39

PC Close Date & Time

29 SEP 2020 12:09

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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 98.3 °F

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

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

PC Time Stamp	29 SEP 2020 17:52
PC Open Date & Time	29 SEP 2020 13:04
PC Close Date & Time	30 SEP 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

97.7 °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

30 SEP 2020 16:44

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 18:10

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 17:54

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

03 OCT 2020 18:06

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 6

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 17:42

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 17:29

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

29 SEP 2020 10:41

PC Open Date & Time

29 SEP 2020 09:39

PC Close Date & Time

29 SEP 2020 12:09

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

29 SEP 2020 17:52

PC Open Date & Time

29 SEP 2020 13:04

PC Close Date & Time

30 SEP 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

30 SEP 2020 16:44

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

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

01 OCT 2020 18:10

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

02 OCT 2020 17:54

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

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

03 OCT 2020 18:06

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

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

04 OCT 2020 17:42

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

05 OCT 2020 17:29

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 10:41
PC Open Date & Time	29 SEP 2020 09:39
PC Close Date & Time	29 SEP 2020 12:09

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 17:52
PC Open Date & Time	29 SEP 2020 13:04
PC Close Date & Time	30 SEP 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 16:44
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 18:11
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

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 ☒

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 17:54
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

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 ☒

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 18:07
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

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 ☒

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EAB) (1725)

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 17:43
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 17:30
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3082122

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:14:41

Generated On: 09 Jun 2021 15:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082122

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:14:41

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082122

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:25

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082122

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	08:10 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 08:10
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3082122

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3082122

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 OCT 2020

Collection time (00:00-23:59)

08:25 (24 HR)

Collection date and time (derived)

30 OCT 2020 08:25

US3082122

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:26

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 OCT 2020 13:39:32
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

03 NOV 2020 05:45:30

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 05:34:20
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 05:43:49
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 06:09:26
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 09:33:55

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

13 DEC 2020 06:15:04

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

19 DEC 2020 11:02:38

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 13:34:57

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 14:53:23

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

09 JAN 2021 10:10:13

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 15:45:32

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

23 JAN 2021 07:34:36

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 12:40:03

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 12:27:29
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 11:20:36

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

20 FEB 2021 08:32:36

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 23:47:14
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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	06 MAR 2021 08:51:16
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	13 MAR 2021 14:09:18
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 08:22:20

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

28 MAR 2021 19:51:43

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

03 APR 2021 08:18:26

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

10 APR 2021 14:16:02

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 APR 2021 10:33:18
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 10:27:23

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

01 MAY 2021 17:38:59

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 <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"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐
Yes ☐

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐
Yes ☐

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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°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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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="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"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 474

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JAN 2022 00:01
Patient Cloud Close Date & Time	12 JAN 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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°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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐
Yes ☐

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JAN 2022 00:01
Patient Cloud Close Date & Time	26 JAN 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

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02 MAR 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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09 MAR 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

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16 MAR 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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°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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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"/>

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Patient Cloud Open Date & Time	27 AUG 2022 00:01
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Patient Cloud Close Date & Time	31 AUG 2022 23:59
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US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	19 OCT 2022 23:59
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US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3082122

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:05:19

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 23:47:21

US3082122

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082122

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082122

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082122

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:12:25

Generated On: 09 Jun 2021 15:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082122

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:12:25

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

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

Visit date (dd MMM yyyy)	26 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3082122

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

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.

US3082122

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3082122

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3082122

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:05:19

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"/>

US3082122

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:05:19

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3082122

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

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

Visit date (dd MMM yyyy)	22 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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US3082122

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3082122

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Height	63.5 in
Weight	118.6 lb
BMI (xxx.x)	20.72274

US3082122

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Height	63.5 in
Weight	118.6 lb
BMI (xxx.x)	20.72274
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)	22 JAN 2021
Time of assessment (00:00-23:59)	08:06 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 08:06
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3082122

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Height	63.5 in
Weight	118.6 lb
BMI (xxx.x)	20.72274
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)	22 JAN 2021
Time of assessment (00:00-23:59)	09:28 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 09:28
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3082122

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 JAN 2021

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

US3082122

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 08:58 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 08:58

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

What was the frequency of the study treatment dosing? ONCE

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

US3082122

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

08:35 (24 HR)

Collection date and time (derived)

22 JAN 2021 08:35

US3082122

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	08:33
Collection Date and Time (derived)	22 JAN 2021 08:33

US3082122

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082122

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

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)	19 FEB 2021
Time of assessment (00:00-23:59)	08:05 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 08:05
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

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)	19 FEB 2021
Time of assessment (00:00-23:59)	08:51 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 08:51
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3082122

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

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.

US3082122

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 19 FEB 2021

What was the treatment time? (00:00-23:59) 08:21 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 08:21

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

US3082122

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:36:20

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:12:25

Generated On: 09 Jun 2021 15:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082122

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:12:25

Generated On: 09 Jun 2021 15:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082122

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:12 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 08:12
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3082122

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3082122

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 MAR 2021
Collection time (00:00-23:59)	08:24 (24 HR)
Collection date and time (derived)	26 MAR 2021 08:24

US3082122

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 16:12:25

Generated On: 09 Jun 2021 15:05:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

AEID	USA-US114-2021-MRNA-1273-P30 1000007
Adverse event	KIDNEY STONES
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)	17 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input 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)	26 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	27 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

THE SUBJECT REPORTED KIDNEY STONES WHICH REQUIRED A TRIP TO THE EMERGENCY ROOM ON 26FEB2021. THE SUBJECT SPOKE TO SITE WHILE IN EMERGENCY ROOM. THE SUBJECT WAS ADMITTED TO HOSPITAL FROM EMERGENCY DEPARTMENT AND WAS DISCHARGED ON 27FEB2021. THE SUBJECT WAS TREATED FOR PAIN WITH IV TORADOL, IV FLUIDS, AND FLOMAX. PT WAS PAIN FREE AT MIDNIGHT AND WAS DISCHARGED. PATIENT REPORTED RESOLUTION OF SYMPTOMS WHEN ON SITE ON 26MAR2021. THE SITE WAS NOT AWARE OF HOSPITAL ADMISSION UNTIL PATIENT REPORTED IT WHILE ON SITE FOR OFFICE VISIT ON 26MAR2021.

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

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 18:14:41

Generated On: 09 Jun 2021 15:05:19

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

Yes ☒

No ☐

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

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PREVENTATIVE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 12:25:08

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Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Name of Medication MAGNESIUM

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Name of Medication IMITREX

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

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 (4)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Name of Medication ALWAY

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGY EYE
DROPS

Dose per administration 1

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

If dose unit is Other, specify DROP PER EYE

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 (5)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input checked="" type="checkbox"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	UN UNK 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Name of Medication EPIPEN

Prophylaxis Yes ☐
No ☒

Indication BANANA ALLERGY AND SHELL
FISH ALLERGY (NEVER BEEN
USED TO DATE)

Dose per administration 0.3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Name of Medication SUMATRIPTAN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONE

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

	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)	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) 26 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 (10)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONE

Dose per administration 8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 12:25:08

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Name of Medication KETOROLAC

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONE

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		03 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3082122

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3082122

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:05:19

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

US3082122

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:05:19

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 ☐

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

SAEID	USA-US114-2021-MRNA-1273-P301000007
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	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

SAEID	USA-US114-2021-MRNA-1273-P301000007
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	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	29/MAR/2021 11:04
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

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 12:25:08

Generated On: 09 Jun 2021 15:05:19

SAEID	USA-US114-2021-MRNA-1273-P301000007
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	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	06/APR/2021 10:23
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

US3082122 (Prod: Trial Management Associates LLC - ERN - PPDS)

US3082122

Form: Participant Creation

Generated On: 09 Jun 2021 15:05:19

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'US3082122'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 12:29:33

US3082122

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:36:56

US3082122

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 12:29:34

US3082122

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Clinic (Clinic)'	Morgan Mathis (b) (4)	27 Aug 2020 12:36:56

US3082122

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'SCRN'	System	27 Aug 2020 12:36:56

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered (b) (6) 1952'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 12:29:35

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '68'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'YEARS'	System	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered '68'	System	27 Aug 2020 12:38:22

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Female (F)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:27:15
User entered 'Male (M)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 19:26:19
User entered 'Female (F)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Morgan Mathis (b) (4)	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'I'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:19

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:37:57

US3082122

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:19

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '27 Aug 2020'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:38:22

US3082122

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'Aug 2020'	System	27 Aug 2020 12:38:22

US3082122

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered '2020'	System	27 Aug 2020 12:38:22

US3082122

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:19

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Amendment 3 (3)'	Morgan Mathis (b) (4)	27 Aug 2020 12:38:22

US3082122

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:38:22

US3082122

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:19

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:38:22

US3082122

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:38:22

US3082122

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:38:22

US3082122

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 12:29:34

US3082122

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'I'	System	27 Aug 2020 12:44:18

US3082122

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:44:18

US3082122

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:05:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:56:17

US3082122

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:22:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:22:22
Data point term sent to Coder	System	27 Aug 2020 14:57:35
User entered 'Migraines'	Morgan Mathis (b) (4)	27 Aug 2020 14:57:04

US3082122

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'UN UNK 2007'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:57:04

US3082122

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:57:04

US3082122

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:57:04

US3082122

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:57:04

US3082122

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:57:04

US3082122

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'Jan 2007'	System	27 Aug 2020 14:57:04

US3082122

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered '2007'	System	27 Aug 2020 14:57:04

US3082122

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered empty.	System	27 Aug 2020 14:57:04

US3082122

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered empty.	System	27 Aug 2020 14:57:04

US3082122

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User closed query 'Per DM CLR: Please review if POST-MENOPAUSAL is a more appropriate MH term to reflect a medical condition/diagnosis as appropriate. If yes, please update and reconcile with the Con Med eCRF as necessary. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 08:38:28
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:06:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:06:34
Query 'Per DM CLR: Please review if POST-MENOPAUSAL is a more appropriate MH term to reflect a medical condition/diagnosis as appropriate. If yes, please update and reconcile with the Con Med eCRF as necessary. ' answered with 'THEH APPROPRIATE TEXT WAS ADDED TO THE MEDICAL HISTORY' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:06:32
Data point term sent to Coder	System	22 Oct 2020 12:05:51
Coding entries removed.	(b) (4), (b) (6)	22 Oct 2020 12:05:22
User entered 'POST MENOPAUSE' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 12:05:22
User opened query 'Per DM CLR: Please review if POST-MENOPAUSAL is a more appropriate MH term to reflect a medical condition/diagnosis as appropriate. If yes, please update and reconcile with the Con Med eCRF as necessary. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:12:56
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:22
Data point term sent to Coder	System	27 Aug 2020 14:57:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3082122

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:19

[Condition](#)

Audit	User	Time (GMT)
User entered 'Menopause'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 14:57:32

US3082122

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'UN UNK 2002'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:57:32

US3082122

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:57:32

US3082122

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Morgan Mathis (b) (4)	16 Dec 2020 14:50:45
User entered 'Yes (Y)'	(b) (4)	
	Morgan Mathis (b) (4)	27 Aug 2020 14:57:32
	(b) (4)	

US3082122

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'un UNK 2002' reason for change:	(b) (4)	
Data Entry Error	Morgan Mathis (b) (4)	16 Dec 2020 14:50:45
User entered empty.	(b) (4)	
	Morgan Mathis (b) (4)	27 Aug 2020 14:57:32
	(b) (4)	

US3082122

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:57:32

US3082122

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'Jan 2002'	System	27 Aug 2020 14:57:32

US3082122

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered '2002'	System	27 Aug 2020 14:57:32

US3082122

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'Jan 2002'	System	16 Dec 2020 14:50:45
User entered empty.	System	27 Aug 2020 14:57:32

US3082122

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered '2002'	System	16 Dec 2020 14:50:45
User entered empty.	System	27 Aug 2020 14:57:32

US3082122

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 13:30:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 13:30:44
Data point term sent to Coder	System	21 Sep 2020 13:29:22
User entered 'Banana Allergy'	Erin Harrelson (b) (4)	21 Sep 2020 13:28:33

US3082122

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'UN UNK 2000'	Erin Harrelson (b) (4)	21 Sep 2020 13:28:33

US3082122

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	Erin Harrelson (b) (4)	21 Sep 2020 13:28:33

US3082122

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	21 Sep 2020 13:28:33

US3082122

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	Erin Harrelson (b) (4)	21 Sep 2020 13:28:33

US3082122

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	Erin Harrelson (b) (4)	21 Sep 2020 13:28:33

US3082122

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'Jan 2000'	System	21 Sep 2020 13:28:33

US3082122

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered '2000'	System	21 Sep 2020 13:28:33

US3082122

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered empty.	System	21 Sep 2020 13:28:33

US3082122

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered empty.	System	21 Sep 2020 13:28:33

US3082122

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Shellfish allergy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 13:30:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 13:30:44
Data point term sent to Coder	System	21 Sep 2020 13:29:22
User entered 'Shell fish allergy'	Erin Harrelson (b) (4)	21 Sep 2020 13:28:51

US3082122

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'UN UNK 2000'	Erin Harrelson (b) (4)	21 Sep 2020 13:28:51

US3082122

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	Erin Harrelson (b) (4)	21 Sep 2020 13:28:51

US3082122

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	21 Sep 2020 13:28:51

US3082122

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	Erin Harrelson (b) (4)	21 Sep 2020 13:28:51

US3082122

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	Erin Harrelson (b) (4)	21 Sep 2020 13:28:51

US3082122

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'Jan 2000'	System	21 Sep 2020 13:28:51

US3082122

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered '2000'	System	21 Sep 2020 13:28:51

US3082122

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered empty.	System	21 Sep 2020 13:28:51

US3082122

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered empty.	System	21 Sep 2020 13:28:51

US3082122

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
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)	21 Sep 2020 13:36:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 13:36:46
Data point term sent to Coder	System	21 Sep 2020 13:35:34
User entered 'Seasonal Allergies'	Erin Harrelson (b) (4)	21 Sep 2020 13:34:41

US3082122

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'UN UNK 2007'	Erin Harrelson (b) (4)	21 Sep 2020 13:34:41

US3082122

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	Erin Harrelson (b) (4)	21 Sep 2020 13:34:41

US3082122

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	21 Sep 2020 13:34:41

US3082122

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	Erin Harrelson (b) (4)	21 Sep 2020 13:34:41

US3082122

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	Erin Harrelson (b) (4)	21 Sep 2020 13:34:41

US3082122

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'Jan 2007'	System	21 Sep 2020 13:34:41

US3082122

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered '2007'	System	21 Sep 2020 13:34:41

US3082122

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered empty.	System	21 Sep 2020 13:34:41

US3082122

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered empty.	System	21 Sep 2020 13:34:41

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:24:06

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '27 Aug 2020'	Morgan Mathis (b) (4)	27 Aug 2020 13:24:06

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '08:49'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:24:06

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered '27 Aug 2020 08:49'	System	27 Aug 2020 13:24:06

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '63.5' in	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:24:06
DataPoint set to visible.	(b) (4) System	27 Aug 2020 12:44:18

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '117.4' lb	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:24:06
DataPoint set to visible.	(b) (4) System	27 Aug 2020 12:44:18

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
Amendment Manager: User entered '20.51306'	System	17 Sep 2020 00:04:49
User entered '20.5'	System	27 Aug 2020 13:24:06
DataPoint set to visible.	System	27 Aug 2020 12:44:18

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'kg/m2'	System	27 Aug 2020 13:24:06
DataPoint set to visible.	System	27 Aug 2020 12:44:18

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 09:13:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 14:08:47
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'DATA HAS BEEN CORRECTED' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 14:08:23
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 04:39:20
User entered '98.3' F	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 13:24:06

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User closed query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 06:03:06
Query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	15 Dec 2020 13:09:57
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	15 Dec 2020 13:09:52
User opened query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 11:33:35
User entered 'Other (Other)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 14:08:47
User entered 'Oral (Oral)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 13:24:06

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4)	15 Dec 2020 13:09:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4)	23 Oct 2020 14:08:47
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 13:24:06

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 14:08:47
User entered '78'	Erin Harrelson (b) (4)	27 Aug 2020 13:24:06
	(b) (4)	

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'bpm'	System	27 Aug 2020 13:24:06

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 14:08:47
User entered '15'	Erin Harrelson (b) (4)	27 Aug 2020 13:24:06
	(b) (4)	

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'breaths/min'	System	27 Aug 2020 13:24:06

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 14:08:47
User entered '148'	Erin Harrelson (b) (4)	27 Aug 2020 13:24:06
	(b) (4)	

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'mmHg'	System	27 Aug 2020 13:24:06

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 14:08:47
User entered '78'	Erin Harrelson (b) (4)	27 Aug 2020 13:24:06
	(b) (4)	

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User entered 'mmHg'	System	27 Aug 2020 13:24:06

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46

US3082122

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46

US3082122

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:20:52

US3082122

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '27 Aug 2020'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:20:52

US3082122

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '27 Aug 2020'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:44:44

US3082122

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:19

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 12:44:44

US3082122

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:19

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Morgan Mathis (b) (4)	27 Aug 2020 12:44:44

US3082122

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:19

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:44:44

US3082122

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:19

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 12:44:44

US3082122

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:19

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	Morgan Mathis (b) (4)	27 Aug 2020 12:44:44

US3082122

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'UN UNK 2002'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 12:44:44

US3082122

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:19

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	Morgan Mathis (b) (4)	27 Aug 2020 12:44:44

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

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)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

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)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

[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)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

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)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

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)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

[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)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

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)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

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)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

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)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

[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)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

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)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'I'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '0'	Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:24

US3082122

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:41

US3082122

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '27 Aug 2020'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:41

US3082122

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Clinic (Clinic)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:41

US3082122

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'VISIT1'	System	27 Aug 2020 13:21:41

US3082122

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 13:24:41

US3082122

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:19

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '188621'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 13:24:41

US3082122

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:19

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 13:24:41

US3082122

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:19

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)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 13:21:53

US3082122

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:19

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)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 13:21:53

US3082122

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:19

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:53

US3082122

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:19

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:53

US3082122

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:19

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:21:53

US3082122

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:19

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	Erin Harrelson (b) (4)	22 Sep 2020 17:25:44
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:11:00
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:10:59

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered missing code ND - Not Done.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered missing code ND - Not Done.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered missing code ND - Not Done.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered missing code ND - Not Done.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User accepted default value 'Pre-Dose (PREDOSE)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Erin Harrelson (b) (4)	23 Oct 2020 14:09:36
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '27 Aug 2020' reason for change: Data Entry Error	(b) (4)	23 Oct 2020 14:09:36
User entered empty.	Erin Harrelson (b) (4)	27 Aug 2020 14:59:15
	(b) (4)	

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '08:49' reason for change: Data Entry Error	(b) (4)	
	Erin Harrelson (b) (4)	23 Oct 2020 14:09:36
User entered empty.	(b) (4)	
	Morgan Mathis (b) (4)	27 Aug 2020 14:59:15
	(b) (4)	

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered '27 Aug 2020 08:49'	System	23 Oct 2020 14:09:36
User entered empty.	System	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '98.3' F reason for change: Data Entry Error	Erin Harrelson (b) (4)	23 Oct 2020 14:09:36
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Oral (Oral)' reason for change: Data Entry Error	Erin Harrelson (b) (4)	23 Oct 2020 14:09:36
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '78' reason for change: Data Entry Error	(b) (4)	
	Erin Harrelson (b) (4)	23 Oct 2020 14:09:36
User entered empty.	(b) (4)	
	Morgan Mathis (b) (4)	27 Aug 2020 14:59:15
	(b) (4)	

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'bpm'	System	23 Oct 2020 14:09:36
User entered empty.	System	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '15' reason for change: Data Entry Error	(b) (4)	
	Erin Harrelson (b) (4)	23 Oct 2020 14:09:36
User entered empty.	(b) (4)	
	Morgan Mathis (b) (4)	27 Aug 2020 14:59:15
	(b) (4)	

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'breaths/min'	System	23 Oct 2020 14:09:36
User entered empty.	System	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '148' reason for change: Data Entry Error	(b) (4)	
	Erin Harrelson (b) (4)	23 Oct 2020 14:09:36
	(b) (4)	
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 14:59:15
	(b) (4)	

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'mmHg'	System	23 Oct 2020 14:09:36
User entered empty.	System	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '78' reason for change: Data Entry Error	(b) (4)	
	Erin Harrelson (b) (4)	23 Oct 2020 14:09:36
	(b) (4)	
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 14:59:15
	(b) (4)	

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'mmHg'	System	23 Oct 2020 14:09:36
User entered empty.	System	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered missing code ND - Not Done.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered missing code ND - Not Done.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User accepted default value 'Post-Dose (POSTDOSE)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '27 Aug 2020'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '10:40'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered '27 Aug 2020 10:40'	System	27 Aug 2020 14:59:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '98.1' F	Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Oral (Oral)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '72'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'bpm'	System	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '14'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'breaths/min'	System	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '145'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'mmHg'	System	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '80'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'mmHg'	System	27 Aug 2020 14:59:15

US3082122

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:29:48

US3082122

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:29:48

US3082122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:25:11

US3082122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:25:11

US3082122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

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)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 14:25:11

US3082122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 14:25:11

US3082122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '27 Aug 2020'	Morgan Mathis (b) (4)	27 Aug 2020 14:25:11

US3082122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '10:09'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:25:11

US3082122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered '27 Aug 2020 10:09'	System	27 Aug 2020 14:25:11

US3082122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Right Arm (RIGHT ARM)'	Morgan Mathis (b) (4)	27 Aug 2020 14:25:11

US3082122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'ONCE'	System	27 Aug 2020 14:25:11

US3082122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 14:25:11

US3082122

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:46:50

US3082122

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '27 Aug 2020'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:46:50

US3082122

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '09:39'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:46:50

US3082122

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered '27 Aug 2020 09:39'	System	27 Aug 2020 13:46:50

US3082122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '27 Aug 2020'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:47:04

US3082122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 13:47:04

US3082122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:47:04

US3082122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '09:44'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:47:04

US3082122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered '27 Aug 2020 09:44'	System	27 Aug 2020 13:47:04

US3082122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 13:47:04

US3082122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:47:04

US3082122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:47:04

US3082122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered empty.	System	27 Aug 2020 13:47:04

US3082122

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 13:59:00

US3082122

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'I'	System	27 Aug 2020 13:59:00

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:40:36', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '52f6252d-6a07-4fa8-a0ba-ab66a4ff1523' User entered 'Yes (Y)'	System	27 Aug 2020 14:41:04
	System	27 Aug 2020 14:41:04

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:40:45', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '52f6252d-6a07-4fa8-a0ba-ab66a4ff1523' User entered '98.1'	System	27 Aug 2020 14:41:04
	System	27 Aug 2020 14:41:04

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:40:50', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '52f6252d-6a07-4fa8-a0ba-ab66a4ff1523'	System	27 Aug 2020 14:41:04
User entered 'No (N)'	System	27 Aug 2020 14:41:04

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '52f6252d-6a07-4fa8-a0ba-ab66a4ff1523' User entered '27 Aug 2020 10:41'	System	27 Aug 2020 14:41:04
	System	27 Aug 2020 14:41:04

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '27 Aug 2020 10:29'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '27 Aug 2020 12:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:55:57', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'fb056b29-b6bb-4984-a7e1-fd3376e12eb2' User entered 'Yes (Y)'	System	27 Aug 2020 21:56:29
	System	27 Aug 2020 21:56:29

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:56:06', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'fb056b29-b6bb-4984-a7e1-fd3376e12eb2' User entered '98.3'	System	27 Aug 2020 21:56:29
	System	27 Aug 2020 21:56:29

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:56:12', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'fb056b29-b6bb-4984-a7e1-fd3376e12eb2'	System	27 Aug 2020 21:56:29
User entered 'No (N)'	System	27 Aug 2020 21:56:29

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:56:24', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'fb056b29-b6bb-4984-a7e1-fd3376e12eb2'	System	27 Aug 2020 21:56:29
User entered '27 Aug 2020 17:56'	System	27 Aug 2020 21:56:29

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '27 Aug 2020 13:54'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 2'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:12:57', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '20a16541-c9ef-4ffd-a65c-b6d0b121c759'	System	28 Aug 2020 22:13:22
User entered 'Yes (Y)'	System	28 Aug 2020 22:13:22

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:13:09', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '20a16541-c9ef-4ffd-a65c-b6d0b121c759' User entered '97.9'	System	28 Aug 2020 22:13:22
	System	28 Aug 2020 22:13:22

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:13:13', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '20a16541-c9ef-4ffd-a65c-b6d0b121c759'	System	28 Aug 2020 22:13:22
User entered 'No (N)'	System	28 Aug 2020 22:13:22

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:13:19', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '20a16541-c9ef-4ffd-a65c-b6d0b121c759' User entered '28 Aug 2020 18:13'	System	28 Aug 2020 22:13:22
	System	28 Aug 2020 22:13:22

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 3'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:25:12', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '54b99ba1-210a-4261-882c-8c14239afa54' User entered 'Yes (Y)'	System	29 Aug 2020 22:25:40
	System	29 Aug 2020 22:25:40

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:25:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '54b99ba1-210a-4261-882c-8c14239afa54' User entered '98.5'	System	29 Aug 2020 22:25:40
	System	29 Aug 2020 22:25:40

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:25:33', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '54b99ba1-210a-4261-882c-8c14239afa54'	System	29 Aug 2020 22:25:40
User entered 'No (N)'	System	29 Aug 2020 22:25:40

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:25:39', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '54b99ba1-210a-4261-882c-8c14239afa54' User entered '29 Aug 2020 18:25'	System	29 Aug 2020 22:25:40
	System	29 Aug 2020 22:25:40

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 4'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:43:29', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c63de4a9-b7c3-48d4-88e1-6c5378c16703' User entered 'Yes (Y)'	System	30 Aug 2020 21:43:58
	System	30 Aug 2020 21:43:58

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:43:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c63de4a9-b7c3-48d4-88e1-6c5378c16703' User entered '98.5'	System	30 Aug 2020 21:43:58
	System	30 Aug 2020 21:43:58

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:43:47', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c63de4a9-b7c3-48d4-88e1-6c5378c16703' User entered 'No (N)'	System	30 Aug 2020 21:43:58
	System	30 Aug 2020 21:43:58

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:43:55', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c63de4a9-b7c3-48d4-88e1-6c5378c16703' User entered '30 Aug 2020 17:43'	System	30 Aug 2020 21:43:58
	System	30 Aug 2020 21:43:58

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 5'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:02:59', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'a530070e-1666-412d-9dfc-525d66b0ad2b' User entered 'Yes (Y)'	System	31 Aug 2020 22:03:19
	System	31 Aug 2020 22:03:19

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:03:07', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'a530070e-1666-412d-9dfc-525d66b0ad2b' User entered '98.6'	System	31 Aug 2020 22:03:19
	System	31 Aug 2020 22:03:19

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:03:10', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'a530070e-1666-412d-9dfc-525d66b0ad2b' User entered 'No (N)'	System	31 Aug 2020 22:03:19
	System	31 Aug 2020 22:03:19

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:03:16', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'a530070e-1666-412d-9dfc-525d66b0ad2b' User entered '31 Aug 2020 18:03'	System	31 Aug 2020 22:03:19
	System	31 Aug 2020 22:03:19

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 6'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:31:19', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'e107bfc8-dcbc-4419-bfd2-f5b8b2cf4d28' User entered 'Yes (Y)'	System	01 Sep 2020 22:31:47
	System	01 Sep 2020 22:31:47

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:31:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'e107bfc8-dcbc-4419-bfd2-f5b8b2cf4d28' User entered '97.7'	System	01 Sep 2020 22:31:47
	System	01 Sep 2020 22:31:47

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:31:33', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'e107bfc8-dcbc-4419-bfd2-f5b8b2cf4d28'	System	01 Sep 2020 22:31:47
User entered 'No (N)'	System	01 Sep 2020 22:31:47

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:31:43', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'e107bfc8-dcbc-4419-bfd2-f5b8b2cf4d28' User entered '01 Sep 2020 18:31'	System	01 Sep 2020 22:31:47
	System	01 Sep 2020 22:31:47

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 7'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:13:01', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '15d4f02b-7baf-4962-8be0-aab96a6bd00a' User entered 'Yes (Y)'	System	02 Sep 2020 22:13:59
	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:13:07', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '15d4f02b-7baf-4962-8be0-aab96a6bd00a' User entered '98.2'	System	02 Sep 2020 22:13:59
	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:13:13', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '15d4f02b-7baf-4962-8be0-aab96a6bd00a' User entered 'Yes (Y)'	System	02 Sep 2020 22:13:59
	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
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 'Patient reports taking Imitrex for migraine. This med is already PRN in con med' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 18:11:36
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.'	Kelsey Heston (b) (4)	03 Sep 2020 16:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:13:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '15d4f02b-7baf-4962-8be0-aab96a6bd00a'	(b) (4)	
User entered '1'	System	02 Sep 2020 22:13:59
	System	02 Sep 2020 22:13:59
	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:13:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '15d4f02b-7baf-4962-8be0-aab96a6bd00a' User entered '0'	System	02 Sep 2020 22:13:59
	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:13:58', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '15d4f02b-7baf-4962-8be0-aab96a6bd00a' User entered '02 Sep 2020 18:13'	System	02 Sep 2020 22:13:59
	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	02 Sep 2020 22:13:59
User entered 'Day 8'	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:05:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	02 Sep 2020 22:13:59
User entered 'Day 9'	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:05:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:08', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '99995b3a-a3c7-4407-a534-954e09755729' User entered 'None (1)'	System	27 Aug 2020 14:41:28
	System	27 Aug 2020 14:41:28

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:12', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '99995b3a-a3c7-4407-a534-954e09755729' User entered 'No (N)'	System	27 Aug 2020 14:41:28
	System	27 Aug 2020 14:41:28

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:14', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '99995b3a-a3c7-4407-a534-954e09755729' User entered 'No (N)'	System	27 Aug 2020 14:41:28
	System	27 Aug 2020 14:41:28

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:18', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '99995b3a-a3c7-4407-a534-954e09755729' User entered 'None (1)'	System	27 Aug 2020 14:41:28
	System	27 Aug 2020 14:41:28

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:24', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '99995b3a-a3c7-4407-a534-954e09755729' User entered '27 Aug 2020 10:41'	System	27 Aug 2020 14:41:28
	System	27 Aug 2020 14:41:28

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '27 Aug 2020 10:29'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '27 Aug 2020 12:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:56:37', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '8d88aeda-b51e-4500-969f-3cba18d1c750' User entered 'None (1)'	System	27 Aug 2020 21:58:10
	System	27 Aug 2020 21:58:10

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:57:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '8d88aeda-b51e-4500-969f-3cba18d1c750' User entered 'No (N)'	System	27 Aug 2020 21:58:10
	System	27 Aug 2020 21:58:10

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:57:39', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '8d88aeda-b51e-4500-969f-3cba18d1c750' User entered 'No (N)'	System	27 Aug 2020 21:58:10
	System	27 Aug 2020 21:58:10

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:57:55', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '8d88aeda-b51e-4500-969f-3cba18d1c750' User entered 'None (1)'	System	27 Aug 2020 21:58:10
	System	27 Aug 2020 21:58:10

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:58:05', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '8d88aeda-b51e-4500-969f-3cba18d1c750' User entered '27 Aug 2020 17:58'	System	27 Aug 2020 21:58:10
	System	27 Aug 2020 21:58:10

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '27 Aug 2020 13:54'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 2'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:13:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '50233aa6-c94d-4e3a-a570-dae3fa3f28cf' User entered 'None (1)'	System	28 Aug 2020 22:13:50
	System	28 Aug 2020 22:13:50

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:13:33', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '50233aa6-c94d-4e3a-a570-dae3fa3f28cf' User entered 'No (N)'	System	28 Aug 2020 22:13:50
	System	28 Aug 2020 22:13:50

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:13:37', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '50233aa6-c94d-4e3a-a570-dae3fa3f28cf' User entered 'No (N)'	System	28 Aug 2020 22:13:50
	System	28 Aug 2020 22:13:50

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:13:40', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '50233aa6-c94d-4e3a-a570-dae3fa3f28cf' User entered 'None (1)'	System	28 Aug 2020 22:13:50
	System	28 Aug 2020 22:13:50

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:13:46', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '50233aa6-c94d-4e3a-a570-dae3fa3f28cf' User entered '28 Aug 2020 18:13'	System	28 Aug 2020 22:13:50
	System	28 Aug 2020 22:13:50

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 3'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:25:46', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '96ef548e-0527-43ee-b4e2-8939645d17df' User entered 'None (1)'	System	29 Aug 2020 22:26:00
	System	29 Aug 2020 22:26:00

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:25:49', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '96ef548e-0527-43ee-b4e2-8939645d17df' User entered 'No (N)'	System	29 Aug 2020 22:26:00
	System	29 Aug 2020 22:26:00

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:25:51', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '96ef548e-0527-43ee-b4e2-8939645d17df' User entered 'No (N)'	System	29 Aug 2020 22:26:00
	System	29 Aug 2020 22:26:00

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:25:54', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '96ef548e-0527-43ee-b4e2-8939645d17df' User entered 'None (1)'	System	29 Aug 2020 22:26:00
	System	29 Aug 2020 22:26:00

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:25:59', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '96ef548e-0527-43ee-b4e2-8939645d17df' User entered '29 Aug 2020 18:25'	System	29 Aug 2020 22:26:00
	System	29 Aug 2020 22:26:00

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 4'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:01', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '9683a6d7-de92-487d-91f0-9ea7882a666f' User entered 'None (1)'	System	30 Aug 2020 21:44:20
	System	30 Aug 2020 21:44:20

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:04', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '9683a6d7-de92-487d-91f0-9ea7882a666f' User entered 'No (N)'	System	30 Aug 2020 21:44:20
	System	30 Aug 2020 21:44:20

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:08', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '9683a6d7-de92-487d-91f0-9ea7882a666f' User entered 'No (N)'	System	30 Aug 2020 21:44:20
	System	30 Aug 2020 21:44:20

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:11', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '9683a6d7-de92-487d-91f0-9ea7882a666f' User entered 'None (1)'	System	30 Aug 2020 21:44:20
	System	30 Aug 2020 21:44:20

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:18', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '9683a6d7-de92-487d-91f0-9ea7882a666f' User entered '30 Aug 2020 17:44'	System	30 Aug 2020 21:44:20
	System	30 Aug 2020 21:44:20

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 5'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:03:27', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c177ccd8-8079-41b5-a97f-3c08df46d171' User entered 'None (1)'	System	31 Aug 2020 22:03:50
	System	31 Aug 2020 22:03:50

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:03:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c177ccd8-8079-41b5-a97f-3c08df46d171' User entered 'No (N)'	System	31 Aug 2020 22:03:50
	System	31 Aug 2020 22:03:50

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:03:33', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c177ccd8-8079-41b5-a97f-3c08df46d171' User entered 'No (N)'	System	31 Aug 2020 22:03:50
	System	31 Aug 2020 22:03:50

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:03:41', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c177ccd8-8079-41b5-a97f-3c08df46d171' User entered 'None (1)'	System	31 Aug 2020 22:03:50
	System	31 Aug 2020 22:03:50

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:03:46', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c177ccd8-8079-41b5-a97f-3c08df46d171' User entered '31 Aug 2020 18:03'	System	31 Aug 2020 22:03:50
	System	31 Aug 2020 22:03:50

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 6'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:31:49', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '43abaa17-1ad1-4a6f-bad2-98da70431ef1' User entered 'None (1)'	System	01 Sep 2020 22:32:05
	System	01 Sep 2020 22:32:05

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:31:53', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '43abaa17-1ad1-4a6f-bad2-98da70431ef1' User entered 'No (N)'	System	01 Sep 2020 22:32:05
	System	01 Sep 2020 22:32:05

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:31:56', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '43abaa17-1ad1-4a6f-bad2-98da70431ef1' User entered 'No (N)'	System	01 Sep 2020 22:32:05
	System	01 Sep 2020 22:32:05

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:31:59', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '43abaa17-1ad1-4a6f-bad2-98da70431ef1' User entered 'None (1)'	System	01 Sep 2020 22:32:05
	System	01 Sep 2020 22:32:05

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:32:04', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '43abaa17-1ad1-4a6f-bad2-98da70431ef1' User entered '01 Sep 2020 18:32'	System	01 Sep 2020 22:32:05
	System	01 Sep 2020 22:32:05

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 7'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:14:04', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '3a72547d-fe4a-4733-aebc-8881bf6fb92f' User entered 'None (1)'	System	02 Sep 2020 22:14:20
	System	02 Sep 2020 22:14:20

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:14:07', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '3a72547d-fe4a-4733-aebc-8881bf6fb92f' User entered 'No (N)'	System	02 Sep 2020 22:14:20
	System	02 Sep 2020 22:14:20

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:14:09', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '3a72547d-fe4a-4733-aebc-8881bf6fb92f' User entered 'No (N)'	System	02 Sep 2020 22:14:20
	System	02 Sep 2020 22:14:20

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:14:13', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '3a72547d-fe4a-4733-aebc-8881bf6fb92f' User entered 'None (1)'	System	02 Sep 2020 22:14:20
	System	02 Sep 2020 22:14:20

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:14:18', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '3a72547d-fe4a-4733-aebc-8881bf6fb92f' User entered '02 Sep 2020 18:14'	System	02 Sep 2020 22:14:20
	System	02 Sep 2020 22:14:20

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:34', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd55a3da3-2c61-4e25-970a-9f5bb7e0d420' User entered 'None (0)'	System	27 Aug 2020 14:42:08
	System	27 Aug 2020 14:42:08

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:38', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd55a3da3-2c61-4e25-970a-9f5bb7e0d420' User entered 'None (0)'	System	27 Aug 2020 14:42:08
	System	27 Aug 2020 14:42:08

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:41', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd55a3da3-2c61-4e25-970a-9f5bb7e0d420' User entered 'None (0)'	System	27 Aug 2020 14:42:08
	System	27 Aug 2020 14:42:08

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd55a3da3-2c61-4e25-970a-9f5bb7e0d420' User entered 'None (0)'	System	27 Aug 2020 14:42:08
	System	27 Aug 2020 14:42:08

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:46', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd55a3da3-2c61-4e25-970a-9f5bb7e0d420' User entered 'None (0)'	System	27 Aug 2020 14:42:08
	System	27 Aug 2020 14:42:08

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:51', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd55a3da3-2c61-4e25-970a-9f5bb7e0d420' User entered 'None (0)'	System	27 Aug 2020 14:42:08
	System	27 Aug 2020 14:42:08

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:41:56', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd55a3da3-2c61-4e25-970a-9f5bb7e0d420' User entered 'No (N)'	System	27 Aug 2020 14:42:08
	System	27 Aug 2020 14:42:08

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T10:42:05', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd55a3da3-2c61-4e25-970a-9f5bb7e0d420' User entered '27 Aug 2020 10:42'	System	27 Aug 2020 14:42:08
	System	27 Aug 2020 14:42:08

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '27 Aug 2020 10:29'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '27 Aug 2020 12:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:58:15', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '744f179f-b59a-4373-80ad-4b9fc13c10b2' User entered 'None (0)'	System	27 Aug 2020 21:58:56
	System	27 Aug 2020 21:58:56

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:58:23', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '744f179f-b59a-4373-80ad-4b9fc13c10b2' User entered 'None (0)'	System	27 Aug 2020 21:58:56
	System	27 Aug 2020 21:58:56

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:58:26', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '744f179f-b59a-4373-80ad-4b9fc13c10b2' User entered 'None (0)'	System	27 Aug 2020 21:58:56
	System	27 Aug 2020 21:58:56

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:58:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '744f179f-b59a-4373-80ad-4b9fc13c10b2' User entered 'None (0)'	System	27 Aug 2020 21:58:56
	System	27 Aug 2020 21:58:56

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:58:33', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '744f179f-b59a-4373-80ad-4b9fc13c10b2' User entered 'None (0)'	System	27 Aug 2020 21:58:56
	System	27 Aug 2020 21:58:56

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:58:36', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '744f179f-b59a-4373-80ad-4b9fc13c10b2' User entered 'None (0)'	System	27 Aug 2020 21:58:56
	System	27 Aug 2020 21:58:56

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:58:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '744f179f-b59a-4373-80ad-4b9fc13c10b2' User entered 'No (N)'	System	27 Aug 2020 21:58:56
	System	27 Aug 2020 21:58:56

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-27T17:58:52', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '744f179f-b59a-4373-80ad-4b9fc13c10b2' User entered '27 Aug 2020 17:58'	System	27 Aug 2020 21:58:56
	System	27 Aug 2020 21:58:56

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '27 Aug 2020 13:54'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 2'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:14:01', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '32db4e51-c491-4aa4-aaf7-ea5120cf3c4c' User entered 'None (0)'	System	28 Aug 2020 22:14:43
	System	28 Aug 2020 22:14:43

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:14:05', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '32db4e51-c491-4aa4-aaf7-ea5120cf3c4c' User entered 'None (0)'	System	28 Aug 2020 22:14:43
	System	28 Aug 2020 22:14:43

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:14:08', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '32db4e51-c491-4aa4-aaf7-ea5120cf3c4c' User entered 'None (0)'	System	28 Aug 2020 22:14:43
	System	28 Aug 2020 22:14:43

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:14:11', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '32db4e51-c491-4aa4-aaf7-ea5120cf3c4c' User entered 'None (0)'	System	28 Aug 2020 22:14:43
	System	28 Aug 2020 22:14:43

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:14:14', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '32db4e51-c491-4aa4-aaf7-ea5120cf3c4c' User entered 'None (0)'	System	28 Aug 2020 22:14:43
	System	28 Aug 2020 22:14:43

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:14:23', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '32db4e51-c491-4aa4-aaf7-ea5120cf3c4c' User entered 'None (0)'	System	28 Aug 2020 22:14:43
	System	28 Aug 2020 22:14:43

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:14:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '32db4e51-c491-4aa4-aaf7-ea5120cf3c4c' User entered 'No (N)'	System	28 Aug 2020 22:14:43
	System	28 Aug 2020 22:14:43

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-28T18:14:38', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '32db4e51-c491-4aa4-aaf7-ea5120cf3c4c' User entered '28 Aug 2020 18:14'	System	28 Aug 2020 22:14:43
	System	28 Aug 2020 22:14:43

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 3'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:26:06', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '515a2195-bd06-4d73-9450-ca0490a3b48f' User entered 'None (0)'	System	29 Aug 2020 22:26:34
	System	29 Aug 2020 22:26:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:26:08', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '515a2195-bd06-4d73-9450-ca0490a3b48f' User entered 'None (0)'	System	29 Aug 2020 22:26:34
	System	29 Aug 2020 22:26:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:26:12', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '515a2195-bd06-4d73-9450-ca0490a3b48f' User entered 'None (0)'	System	29 Aug 2020 22:26:34
	System	29 Aug 2020 22:26:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:26:15', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '515a2195-bd06-4d73-9450-ca0490a3b48f' User entered 'None (0)'	System	29 Aug 2020 22:26:34
	System	29 Aug 2020 22:26:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:26:17', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '515a2195-bd06-4d73-9450-ca0490a3b48f' User entered 'None (0)'	System	29 Aug 2020 22:26:34
	System	29 Aug 2020 22:26:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:26:20', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '515a2195-bd06-4d73-9450-ca0490a3b48f' User entered 'None (0)'	System	29 Aug 2020 22:26:34
	System	29 Aug 2020 22:26:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:26:23', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '515a2195-bd06-4d73-9450-ca0490a3b48f' User entered 'No (N)'	System	29 Aug 2020 22:26:34
	System	29 Aug 2020 22:26:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-29T18:26:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '515a2195-bd06-4d73-9450-ca0490a3b48f' User entered '29 Aug 2020 18:26'	System	29 Aug 2020 22:26:34
	System	29 Aug 2020 22:26:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 4'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:24', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '29152d3a-23a2-4616-b0b6-170976fd0722' User entered 'None (0)'	System	30 Aug 2020 21:44:52
	System	30 Aug 2020 21:44:52

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:28', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '29152d3a-23a2-4616-b0b6-170976fd0722' User entered 'None (0)'	System	30 Aug 2020 21:44:52
	System	30 Aug 2020 21:44:52

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '29152d3a-23a2-4616-b0b6-170976fd0722' User entered 'None (0)'	System	30 Aug 2020 21:44:52
	System	30 Aug 2020 21:44:52

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:32', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '29152d3a-23a2-4616-b0b6-170976fd0722' User entered 'None (0)'	System	30 Aug 2020 21:44:52
	System	30 Aug 2020 21:44:52

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:35', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '29152d3a-23a2-4616-b0b6-170976fd0722' User entered 'None (0)'	System	30 Aug 2020 21:44:52
	System	30 Aug 2020 21:44:52

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:38', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '29152d3a-23a2-4616-b0b6-170976fd0722' User entered 'None (0)'	System	30 Aug 2020 21:44:52
	System	30 Aug 2020 21:44:52

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '29152d3a-23a2-4616-b0b6-170976fd0722'	System	30 Aug 2020 21:44:52
User entered 'No (N)'	System	30 Aug 2020 21:44:52

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-30T17:44:48', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '29152d3a-23a2-4616-b0b6-170976fd0722' User entered '30 Aug 2020 17:44'	System	30 Aug 2020 21:44:52
	System	30 Aug 2020 21:44:52

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 5'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:03:53', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6c8d2ec8-3eff-4612-b080-3500af419b12' User entered 'None (0)'	System	31 Aug 2020 22:04:19
	System	31 Aug 2020 22:04:19

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:03:56', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6c8d2ec8-3eff-4612-b080-3500af419b12' User entered 'None (0)'	System	31 Aug 2020 22:04:19
	System	31 Aug 2020 22:04:19

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:03:58', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6c8d2ec8-3eff-4612-b080-3500af419b12' User entered 'None (0)'	System	31 Aug 2020 22:04:19
	System	31 Aug 2020 22:04:19

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:04:01', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6c8d2ec8-3eff-4612-b080-3500af419b12' User entered 'None (0)'	System	31 Aug 2020 22:04:19
	System	31 Aug 2020 22:04:19

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:04:04', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6c8d2ec8-3eff-4612-b080-3500af419b12' User entered 'None (0)'	System	31 Aug 2020 22:04:19
	System	31 Aug 2020 22:04:19

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:04:06', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6c8d2ec8-3eff-4612-b080-3500af419b12'	System	31 Aug 2020 22:04:19
User entered 'None (0)'	System	31 Aug 2020 22:04:19

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:04:10', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6c8d2ec8-3eff-4612-b080-3500af419b12'	System	31 Aug 2020 22:04:19
User entered 'No (N)'	System	31 Aug 2020 22:04:19

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-08-31T18:04:17', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6c8d2ec8-3eff-4612-b080-3500af419b12' User entered '31 Aug 2020 18:04'	System	31 Aug 2020 22:04:19
	System	31 Aug 2020 22:04:19

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 6'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:32:08', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '297baafb-4769-4042-97a7-03377f5b542f' User entered 'None (0)'	System	01 Sep 2020 22:32:39
	System	01 Sep 2020 22:32:39

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:32:11', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '297baafb-4769-4042-97a7-03377f5b542f' User entered 'None (0)'	System	01 Sep 2020 22:32:39
	System	01 Sep 2020 22:32:39

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:32:14', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '297baafb-4769-4042-97a7-03377f5b542f' User entered 'None (0)'	System	01 Sep 2020 22:32:39
	System	01 Sep 2020 22:32:39

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:32:16', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '297baafb-4769-4042-97a7-03377f5b542f' User entered 'None (0)'	System	01 Sep 2020 22:32:39
	System	01 Sep 2020 22:32:39

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:32:18', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '297baafb-4769-4042-97a7-03377f5b542f' User entered 'None (0)'	System	01 Sep 2020 22:32:39
	System	01 Sep 2020 22:32:39

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:32:21', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '297baafb-4769-4042-97a7-03377f5b542f' User entered 'None (0)'	System	01 Sep 2020 22:32:39
	System	01 Sep 2020 22:32:39

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:32:26', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '297baafb-4769-4042-97a7-03377f5b542f' User entered 'No (N)'	System	01 Sep 2020 22:32:39
	System	01 Sep 2020 22:32:39

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-01T18:32:35', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '297baafb-4769-4042-97a7-03377f5b542f' User entered '01 Sep 2020 18:32'	System	01 Sep 2020 22:32:39
	System	01 Sep 2020 22:32:39

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 7'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:14:51', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '22d42dd4-649f-4729-9427-17392e6b1975'	System	02 Sep 2020 22:15:34
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:14:56', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '22d42dd4-649f-4729-9427-17392e6b1975'	System	02 Sep 2020 22:15:34
User entered 'None (0)'	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:14:59', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '22d42dd4-649f-4729-9427-17392e6b1975' User entered 'None (0)'	System	02 Sep 2020 22:15:34
	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:15:01', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '22d42dd4-649f-4729-9427-17392e6b1975' User entered 'None (0)'	System	02 Sep 2020 22:15:34
	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:15:06', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '22d42dd4-649f-4729-9427-17392e6b1975' User entered 'None (0)'	System	02 Sep 2020 22:15:34
	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:15:09', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '22d42dd4-649f-4729-9427-17392e6b1975'	System	02 Sep 2020 22:15:34
User entered 'None (0)'	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:15:16', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '22d42dd4-649f-4729-9427-17392e6b1975'	System	02 Sep 2020 22:15:34
User entered 'No (N)'	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-02T18:15:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '22d42dd4-649f-4729-9427-17392e6b1975'	System	02 Sep 2020 22:15:34
User entered '02 Sep 2020 18:15'	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	02 Sep 2020 22:15:34
User entered 'Day 8'	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:05:19

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	02 Sep 2020 22:15:34
User entered 'Day 9'	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:05:19

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:15:34

US3082122

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	02 Sep 2020 22:13:59
User entered 'Day 8'	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	02 Sep 2020 22:13:59
User entered 'Day 9'	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27

US3082122

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:13:59

US3082122

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:13:59

US3082122

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) Kelsey Heston (b) (4)	03 Sep 2020 16:35:30

US3082122

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '3 Sep 2020'	Kelsey Heston (b) (4)	03 Sep 2020 16:35:30

US3082122

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Contact Made (CONTACT MADE)'	Kelsey Heston (b) (4)	03 Sep 2020 16:35:30

US3082122

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	Kelsey Heston (b) (4)	03 Sep 2020 16:35:30

US3082122

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) Kelsey Heston (b) (4)	03 Sep 2020 16:35:35

US3082122

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'I'	System	03 Sep 2020 16:35:35

US3082122

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'Yes (Y)'	(b) (4) Angie Northcott (b) (4)	10 Sep 2020 17:43:00

US3082122

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered '10 Sep 2020'	(b) (4) Angie Northcott (b) (4)	10 Sep 2020 17:43:00

US3082122

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Angie Northcott (b) (4)	10 Sep 2020 17:43:00

US3082122

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered empty.	(b) (4) Angie Northcott (b) (4)	10 Sep 2020 17:43:00

US3082122

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'Yes (Y)'	(b) (4) Angie Northcott (b) (4)	10 Sep 2020 17:43:04

US3082122

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'I'	System	10 Sep 2020 17:43:04

US3082122

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	17 Sep 2020 14:26:41

US3082122

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered '17 Sep 2020'	Erin Harrelson (b) (4)	17 Sep 2020 14:26:41

US3082122

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4)	17 Sep 2020 14:26:41

US3082122

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Erin Harrelson (b) (4)	17 Sep 2020 14:26:41

US3082122

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	17 Sep 2020 14:26:48

US3082122

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'I'	System	17 Sep 2020 14:26:48

US3082122

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Brandy Lowman (b) (4)	29 Sep 2020 12:22:17

US3082122

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '29 Sep 2020'	(b) (4) Brandy Lowman (b) (4)	29 Sep 2020 12:22:17

US3082122

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Clinic (Clinic)'	(b) (4) Brandy Lowman (b) (4)	29 Sep 2020 12:22:17

US3082122

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'VISIT2'	System	29 Sep 2020 12:22:17

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User accepted default value 'Pre-Dose (PREDOSE)'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '29 Sep 2020'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '07:56'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered '29 Sep 2020 07:56'	System	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '97.5' F	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Other (Other)'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'forehead'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '74'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'bpm'	System	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '14'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'breaths/min'	System	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '134'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'mmHg'	System	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '76'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'mmHg'	System	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User accepted default value 'Post-Dose (POSTDOSE)'	Erin Harrelson (b) (4) (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '29 Sep 2020'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '09:50'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered '29 Sep 2020 09:50'	System	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '97.8' F	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Oral (Oral)'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '77'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'bpm'	System	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '15'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'breaths/min'	System	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '134'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'mmHg'	System	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '81'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'mmHg'	System	29 Sep 2020 14:02:04

US3082122

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Brandy Lowman (b) (4)	29 Sep 2020 12:42:24

US3082122

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '29 Sep 2020'	(b) (4) Brandy Lowman (b) (4)	29 Sep 2020 12:42:24

US3082122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:56

US3082122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	Erin Harrelson (b) (4)	29 Sep 2020 14:02:56

US3082122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

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)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	Erin Harrelson (b) (4)	29 Sep 2020 14:02:56

US3082122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 14:02:56

US3082122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '29 Sep 2020'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:56

US3082122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '09:19'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:56

US3082122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered '29 Sep 2020 09:19'	System	29 Sep 2020 14:02:56

US3082122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Right Arm (RIGHT ARM)'	Erin Harrelson (b) (4)	29 Sep 2020 14:02:56

US3082122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'ONCE'	System	29 Sep 2020 14:02:56

US3082122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 14:02:56

US3082122

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	29 Sep 2020 14:03:42

US3082122

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '29 Sep 2020'	Erin Harrelson (b) (4)	29 Sep 2020 14:03:42

US3082122

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '09:05'	Erin Harrelson (b) (4)	29 Sep 2020 14:03:42

US3082122

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered '29 Sep 2020 09:05'	System	29 Sep 2020 14:03:42

US3082122

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '29 Sep 2020'	Erin Harrelson (b) (4)	29 Sep 2020 14:03:57

US3082122

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erin Harrelson (b) (4)	29 Sep 2020 14:03:57

US3082122

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	29 Sep 2020 14:03:57

US3082122

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '09:08'	Erin Harrelson (b) (4)	29 Sep 2020 14:03:57

US3082122

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered '29 Sep 2020 09:08'	System	29 Sep 2020 14:03:57

US3082122

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erin Harrelson (b) (4)	29 Sep 2020 14:03:57

US3082122

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'No (N)'	Erin Harrelson (b) (4)	29 Sep 2020 14:03:57

US3082122

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	Erin Harrelson (b) (4)	29 Sep 2020 14:03:57

US3082122

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered empty.	System	29 Sep 2020 14:03:57

US3082122

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	29 Sep 2020 14:04:01

US3082122

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'I'	System	29 Sep 2020 14:04:01

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:40:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '27246b19-bd60-4714-b20c-8b97e861f89e' User entered 'Yes (Y)'	System	29 Sep 2020 14:41:05
	System	29 Sep 2020 14:41:05

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:40:56', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '27246b19-bd60-4714-b20c-8b97e861f89e' User entered '97.8'	System	29 Sep 2020 14:41:05
	System	29 Sep 2020 14:41:05

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:40:59', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '27246b19-bd60-4714-b20c-8b97e861f89e' User entered 'No (N)'	System	29 Sep 2020 14:41:05
	System	29 Sep 2020 14:41:05

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:02', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '27246b19-bd60-4714-b20c-8b97e861f89e' User entered '29 Sep 2020 10:41'	System	29 Sep 2020 14:41:05
	System	29 Sep 2020 14:41:05

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Sep 2020 09:39'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Sep 2020 12:09'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c2d0886a-ba6c-45f7-929a-f81ff7d38e46' User entered 'Yes (Y)'	System	29 Sep 2020 21:52:18
	System	29 Sep 2020 21:52:18

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:06', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c2d0886a-ba6c-45f7-929a-f81ff7d38e46' User entered '98.3'	System	29 Sep 2020 21:52:18
	System	29 Sep 2020 21:52:18

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:09', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c2d0886a-ba6c-45f7-929a-f81ff7d38e46'	System	29 Sep 2020 21:52:18
User entered 'No (N)'	System	29 Sep 2020 21:52:18

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:14', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c2d0886a-ba6c-45f7-929a-f81ff7d38e46' User entered '29 Sep 2020 17:52'	System	29 Sep 2020 21:52:18
	System	29 Sep 2020 21:52:18

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Sep 2020 13:04'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 2'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:43:55', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '2b043d4f-6cb0-41cd-b9f5-28774cb80942' User entered 'Yes (Y)'	System	30 Sep 2020 20:44:11
	System	30 Sep 2020 20:44:11

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:01', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '2b043d4f-6cb0-41cd-b9f5-28774cb80942' User entered '97.7'	System	30 Sep 2020 20:44:11
	System	30 Sep 2020 20:44:11

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:04', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '2b043d4f-6cb0-41cd-b9f5-28774cb80942'	System	30 Sep 2020 20:44:11
User entered 'No (N)'	System	30 Sep 2020 20:44:11

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:08', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '2b043d4f-6cb0-41cd-b9f5-28774cb80942' User entered '30 Sep 2020 16:44'	System	30 Sep 2020 20:44:11
	System	30 Sep 2020 20:44:11

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 3'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:10:24', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5932d2a6-354d-4662-a784-31e7e3a0fee4' User entered 'Yes (Y)'	System	01 Oct 2020 22:10:38
	System	01 Oct 2020 22:10:38

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:10:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5932d2a6-354d-4662-a784-31e7e3a0fee4' User entered '98.2'	System	01 Oct 2020 22:10:38
	System	01 Oct 2020 22:10:38

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:10:33', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5932d2a6-354d-4662-a784-31e7e3a0fee4' User entered 'No (N)'	System	01 Oct 2020 22:10:38
	System	01 Oct 2020 22:10:38

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:10:36', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5932d2a6-354d-4662-a784-31e7e3a0fee4' User entered '01 Oct 2020 18:10'	System	01 Oct 2020 22:10:38
	System	01 Oct 2020 22:10:38

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 4'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:01', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '7609458b-4a29-40f0-8d35-02ecb0455605' User entered 'Yes (Y)'	System	02 Oct 2020 21:54:16
	System	02 Oct 2020 21:54:16

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:07', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '7609458b-4a29-40f0-8d35-02ecb0455605' User entered '98.6'	System	02 Oct 2020 21:54:16
	System	02 Oct 2020 21:54:16

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:10', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '7609458b-4a29-40f0-8d35-02ecb0455605' User entered 'No (N)'	System	02 Oct 2020 21:54:16
	System	02 Oct 2020 21:54:16

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:12', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '7609458b-4a29-40f0-8d35-02ecb0455605' User entered '02 Oct 2020 17:54'	System	02 Oct 2020 21:54:16
	System	02 Oct 2020 21:54:16

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 5'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:09', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'f2aaec66-c520-4667-bc09-ef3b8f64eb87' User entered 'Yes (Y)'	System	03 Oct 2020 22:06:23
	System	03 Oct 2020 22:06:23

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:14', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'f2aaec66-c520-4667-bc09-ef3b8f64eb87' User entered '98.0'	System	03 Oct 2020 22:06:23
	System	03 Oct 2020 22:06:23

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:17', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'f2aaec66-c520-4667-bc09-ef3b8f64eb87'	System	03 Oct 2020 22:06:23
User entered 'No (N)'	System	03 Oct 2020 22:06:23

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:21', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'f2aaec66-c520-4667-bc09-ef3b8f64eb87' User entered '03 Oct 2020 18:06'	System	03 Oct 2020 22:06:23
	System	03 Oct 2020 22:06:23

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 6'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:42:27', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '048cd112-82e4-4e08-9e32-5f7b7a9e65b8' User entered 'Yes (Y)'	System	04 Oct 2020 21:42:39
	System	04 Oct 2020 21:42:39

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:42:32', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '048cd112-82e4-4e08-9e32-5f7b7a9e65b8' User entered '98.3'	System	04 Oct 2020 21:42:39
	System	04 Oct 2020 21:42:39

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:42:34', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '048cd112-82e4-4e08-9e32-5f7b7a9e65b8' User entered 'No (N)'	System	04 Oct 2020 21:42:39
	System	04 Oct 2020 21:42:39

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:42:38', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '048cd112-82e4-4e08-9e32-5f7b7a9e65b8' User entered '04 Oct 2020 17:42'	System	04 Oct 2020 21:42:39
	System	04 Oct 2020 21:42:39

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 7'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:16', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '9f97ee4c-83de-4a5e-87bf-10a4291c29eb' User entered 'Yes (Y)'	System	05 Oct 2020 21:29:29
	System	05 Oct 2020 21:29:29

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:21', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '9f97ee4c-83de-4a5e-87bf-10a4291c29eb' User entered '98.4'	System	05 Oct 2020 21:29:29
	System	05 Oct 2020 21:29:29

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:24', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '9f97ee4c-83de-4a5e-87bf-10a4291c29eb'	System	05 Oct 2020 21:29:29
User entered 'No (N)'	System	05 Oct 2020 21:29:29

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:27', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '9f97ee4c-83de-4a5e-87bf-10a4291c29eb' User entered '05 Oct 2020 17:29'	System	05 Oct 2020 21:29:29
	System	05 Oct 2020 21:29:29

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:06', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '1082f9c9-5c02-4b77-b40f-ec8b5c1ea651'	System	29 Sep 2020 14:41:17
User entered 'None (1)'	System	29 Sep 2020 14:41:17

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:08', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '1082f9c9-5c02-4b77-b40f-ec8b5c1ea651' User entered 'No (N)'	System	29 Sep 2020 14:41:17
	System	29 Sep 2020 14:41:17

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:11', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '1082f9c9-5c02-4b77-b40f-ec8b5c1ea651' User entered 'No (N)'	System	29 Sep 2020 14:41:17
	System	29 Sep 2020 14:41:17

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:13', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '1082f9c9-5c02-4b77-b40f-ec8b5c1ea651' User entered 'None (1)'	System	29 Sep 2020 14:41:17
	System	29 Sep 2020 14:41:17

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:15', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '1082f9c9-5c02-4b77-b40f-ec8b5c1ea651' User entered '29 Sep 2020 10:41'	System	29 Sep 2020 14:41:17
	System	29 Sep 2020 14:41:17

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Sep 2020 09:39'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Sep 2020 12:09'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:20', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c5c715e1-a116-44f8-8471-2c01eb018bab' User entered 'None (1)'	System	29 Sep 2020 21:52:36
	System	29 Sep 2020 21:52:36

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:23', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c5c715e1-a116-44f8-8471-2c01eb018bab' User entered 'No (N)'	System	29 Sep 2020 21:52:36
	System	29 Sep 2020 21:52:36

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:25', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c5c715e1-a116-44f8-8471-2c01eb018bab' User entered 'No (N)'	System	29 Sep 2020 21:52:36
	System	29 Sep 2020 21:52:36

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:29', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c5c715e1-a116-44f8-8471-2c01eb018bab' User entered 'None (1)'	System	29 Sep 2020 21:52:36
	System	29 Sep 2020 21:52:36

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:32', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'c5c715e1-a116-44f8-8471-2c01eb018bab' User entered '29 Sep 2020 17:52'	System	29 Sep 2020 21:52:36
	System	29 Sep 2020 21:52:36

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Sep 2020 13:04'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 2'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:19', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b8de8a77-1bf8-4be9-a82a-d4cec1e81fa4'	System	30 Sep 2020 20:44:34
User entered 'None (1)'	System	30 Sep 2020 20:44:34

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:21', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b8de8a77-1bf8-4be9-a82a-d4cec1e81fa4' User entered 'No (N)'	System	30 Sep 2020 20:44:34
	System	30 Sep 2020 20:44:34

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:23', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b8de8a77-1bf8-4be9-a82a-d4cec1e81fa4' User entered 'No (N)'	System	30 Sep 2020 20:44:34
	System	30 Sep 2020 20:44:34

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:27', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b8de8a77-1bf8-4be9-a82a-d4cec1e81fa4'	System	30 Sep 2020 20:44:34
User entered 'None (1)'	System	30 Sep 2020 20:44:34

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:31', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b8de8a77-1bf8-4be9-a82a-d4cec1e81fa4' User entered '30 Sep 2020 16:44'	System	30 Sep 2020 20:44:34
	System	30 Sep 2020 20:44:34

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 3'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:10:40', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5e884b8a-d299-4fc1-a5c3-a7ef3420d8de' User entered 'None (1)'	System	01 Oct 2020 22:10:59
	System	01 Oct 2020 22:10:59

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:10:43', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5e884b8a-d299-4fc1-a5c3-a7ef3420d8de' User entered 'No (N)'	System	01 Oct 2020 22:10:59
	System	01 Oct 2020 22:10:59

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:10:46', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5e884b8a-d299-4fc1-a5c3-a7ef3420d8de' User entered 'No (N)'	System	01 Oct 2020 22:10:59
	System	01 Oct 2020 22:10:59

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:10:49', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5e884b8a-d299-4fc1-a5c3-a7ef3420d8de' User entered 'None (1)'	System	01 Oct 2020 22:10:59
	System	01 Oct 2020 22:10:59

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:10:56', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5e884b8a-d299-4fc1-a5c3-a7ef3420d8de' User entered '01 Oct 2020 18:10'	System	01 Oct 2020 22:10:59
	System	01 Oct 2020 22:10:59

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 4'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:18', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '3c1fbef4-059c-4d34-937a-dea8f26e755d'	System	02 Oct 2020 21:54:37
User entered 'None (1)'	System	02 Oct 2020 21:54:37

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:26', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '3c1fbef4-059c-4d34-937a-dea8f26e755d' User entered 'No (N)'	System	02 Oct 2020 21:54:37
	System	02 Oct 2020 21:54:37

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:28', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '3c1fbef4-059c-4d34-937a-dea8f26e755d' User entered 'No (N)'	System	02 Oct 2020 21:54:37
	System	02 Oct 2020 21:54:37

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:31', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '3c1fbef4-059c-4d34-937a-dea8f26e755d' User entered 'None (1)'	System	02 Oct 2020 21:54:37
	System	02 Oct 2020 21:54:37

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:35', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '3c1fbef4-059c-4d34-937a-dea8f26e755d' User entered '02 Oct 2020 17:54'	System	02 Oct 2020 21:54:37
	System	02 Oct 2020 21:54:37

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 5'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:25', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd29f7f98-de3e-4c0f-8171-53314f6a4b64'	System	03 Oct 2020 22:06:41
User entered 'None (1)'	System	03 Oct 2020 22:06:41

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:28', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd29f7f98-de3e-4c0f-8171-53314f6a4b64' User entered 'No (N)'	System	03 Oct 2020 22:06:41
	System	03 Oct 2020 22:06:41

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd29f7f98-de3e-4c0f-8171-53314f6a4b64' User entered 'No (N)'	System	03 Oct 2020 22:06:41
	System	03 Oct 2020 22:06:41

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:33', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd29f7f98-de3e-4c0f-8171-53314f6a4b64'	System	03 Oct 2020 22:06:41
User entered 'None (1)'	System	03 Oct 2020 22:06:41

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:39', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd29f7f98-de3e-4c0f-8171-53314f6a4b64' User entered '03 Oct 2020 18:06'	System	03 Oct 2020 22:06:41
	System	03 Oct 2020 22:06:41

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 6'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:42:42', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'dd00ac43-a1a1-46dc-be57-965b1ab3077c' User entered 'None (1)'	System	04 Oct 2020 21:42:54
	System	04 Oct 2020 21:42:54

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:42:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'dd00ac43-a1a1-46dc-be57-965b1ab3077c' User entered 'No (N)'	System	04 Oct 2020 21:42:54
	System	04 Oct 2020 21:42:54

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:42:46', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'dd00ac43-a1a1-46dc-be57-965b1ab3077c' User entered 'No (N)'	System	04 Oct 2020 21:42:54
	System	04 Oct 2020 21:42:54

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:42:49', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'dd00ac43-a1a1-46dc-be57-965b1ab3077c' User entered 'None (1)'	System	04 Oct 2020 21:42:54
	System	04 Oct 2020 21:42:54

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:42:51', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'dd00ac43-a1a1-46dc-be57-965b1ab3077c' User entered '04 Oct 2020 17:42'	System	04 Oct 2020 21:42:54
	System	04 Oct 2020 21:42:54

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 7'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:32', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '1f428c61-c076-4a4b-aaca-537750acd8b9' User entered 'None (1)'	System	05 Oct 2020 21:29:47
	System	05 Oct 2020 21:29:47

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:34', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '1f428c61-c076-4a4b-aaca-537750acd8b9' User entered 'No (N)'	System	05 Oct 2020 21:29:47
	System	05 Oct 2020 21:29:47

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:36', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '1f428c61-c076-4a4b-aaca-537750acd8b9' User entered 'No (N)'	System	05 Oct 2020 21:29:47
	System	05 Oct 2020 21:29:47

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:40', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '1f428c61-c076-4a4b-aaca-537750acd8b9' User entered 'None (1)'	System	05 Oct 2020 21:29:47
	System	05 Oct 2020 21:29:47

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '1f428c61-c076-4a4b-aaca-537750acd8b9' User entered '05 Oct 2020 17:29'	System	05 Oct 2020 21:29:47
	System	05 Oct 2020 21:29:47

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:19', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b3be8029-2da6-4bd3-91e9-c0f1806a12df' User entered 'None (0)'	System	29 Sep 2020 14:41:40
	System	29 Sep 2020 14:41:40

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:21', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b3be8029-2da6-4bd3-91e9-c0f1806a12df' User entered 'None (0)'	System	29 Sep 2020 14:41:40
	System	29 Sep 2020 14:41:40

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:23', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b3be8029-2da6-4bd3-91e9-c0f1806a12df' User entered 'None (0)'	System	29 Sep 2020 14:41:40
	System	29 Sep 2020 14:41:40

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:25', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b3be8029-2da6-4bd3-91e9-c0f1806a12df' User entered 'None (0)'	System	29 Sep 2020 14:41:40
	System	29 Sep 2020 14:41:40

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:27', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b3be8029-2da6-4bd3-91e9-c0f1806a12df' User entered 'None (0)'	System	29 Sep 2020 14:41:40
	System	29 Sep 2020 14:41:40

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:29', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b3be8029-2da6-4bd3-91e9-c0f1806a12df' User entered 'None (0)'	System	29 Sep 2020 14:41:40
	System	29 Sep 2020 14:41:40

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:31', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b3be8029-2da6-4bd3-91e9-c0f1806a12df' User entered 'No (N)'	System	29 Sep 2020 14:41:40
	System	29 Sep 2020 14:41:40

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T10:41:34', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b3be8029-2da6-4bd3-91e9-c0f1806a12df' User entered '29 Sep 2020 10:41'	System	29 Sep 2020 14:41:40
	System	29 Sep 2020 14:41:40

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Sep 2020 09:39'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Sep 2020 12:09'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:37', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '12b2a242-664f-40d2-8ee5-015fd422f13d' User entered 'None (0)'	System	29 Sep 2020 21:53:03
	System	29 Sep 2020 21:53:03

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:42', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '12b2a242-664f-40d2-8ee5-015fd422f13d' User entered 'None (0)'	System	29 Sep 2020 21:53:03
	System	29 Sep 2020 21:53:03

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '12b2a242-664f-40d2-8ee5-015fd422f13d' User entered 'None (0)'	System	29 Sep 2020 21:53:03
	System	29 Sep 2020 21:53:03

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:46', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '12b2a242-664f-40d2-8ee5-015fd422f13d' User entered 'None (0)'	System	29 Sep 2020 21:53:03
	System	29 Sep 2020 21:53:03

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:49', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '12b2a242-664f-40d2-8ee5-015fd422f13d' User entered 'None (0)'	System	29 Sep 2020 21:53:03
	System	29 Sep 2020 21:53:03

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:51', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '12b2a242-664f-40d2-8ee5-015fd422f13d' User entered 'None (0)'	System	29 Sep 2020 21:53:03
	System	29 Sep 2020 21:53:03

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:56', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '12b2a242-664f-40d2-8ee5-015fd422f13d' User entered 'No (N)'	System	29 Sep 2020 21:53:03
	System	29 Sep 2020 21:53:03

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-29T17:52:59', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '12b2a242-664f-40d2-8ee5-015fd422f13d' User entered '29 Sep 2020 17:52'	System	29 Sep 2020 21:53:03
	System	29 Sep 2020 21:53:03

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '29 Sep 2020 13:04'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 2'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:35', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '4a3deb2f-56b8-4508-a429-75585246f03d' User entered 'None (0)'	System	30 Sep 2020 20:44:55
	System	30 Sep 2020 20:44:55

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:37', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '4a3deb2f-56b8-4508-a429-75585246f03d' User entered 'None (0)'	System	30 Sep 2020 20:44:55
	System	30 Sep 2020 20:44:55

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:39', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '4a3deb2f-56b8-4508-a429-75585246f03d' User entered 'None (0)'	System	30 Sep 2020 20:44:55
	System	30 Sep 2020 20:44:55

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:42', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '4a3deb2f-56b8-4508-a429-75585246f03d' User entered 'None (0)'	System	30 Sep 2020 20:44:55
	System	30 Sep 2020 20:44:55

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '4a3deb2f-56b8-4508-a429-75585246f03d' User entered 'None (0)'	System	30 Sep 2020 20:44:55
	System	30 Sep 2020 20:44:55

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:46', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '4a3deb2f-56b8-4508-a429-75585246f03d' User entered 'None (0)'	System	30 Sep 2020 20:44:55
	System	30 Sep 2020 20:44:55

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:50', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '4a3deb2f-56b8-4508-a429-75585246f03d' User entered 'No (N)'	System	30 Sep 2020 20:44:55
	System	30 Sep 2020 20:44:55

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-09-30T16:44:52', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '4a3deb2f-56b8-4508-a429-75585246f03d' User entered '30 Sep 2020 16:44'	System	30 Sep 2020 20:44:55
	System	30 Sep 2020 20:44:55

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 3'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:11:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0ddf7a02-a86f-489d-9b6c-78f487f502be' User entered 'None (0)'	System	01 Oct 2020 22:11:25
	System	01 Oct 2020 22:11:25

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:11:03', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0ddf7a02-a86f-489d-9b6c-78f487f502be' User entered 'None (0)'	System	01 Oct 2020 22:11:25
	System	01 Oct 2020 22:11:25

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:11:05', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0ddf7a02-a86f-489d-9b6c-78f487f502be' User entered 'None (0)'	System	01 Oct 2020 22:11:25
	System	01 Oct 2020 22:11:25

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:11:08', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0ddf7a02-a86f-489d-9b6c-78f487f502be' User entered 'None (0)'	System	01 Oct 2020 22:11:25
	System	01 Oct 2020 22:11:25

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:11:10', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0ddf7a02-a86f-489d-9b6c-78f487f502be' User entered 'None (0)'	System	01 Oct 2020 22:11:25
	System	01 Oct 2020 22:11:25

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:11:12', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0ddf7a02-a86f-489d-9b6c-78f487f502be' User entered 'None (0)'	System	01 Oct 2020 22:11:25
	System	01 Oct 2020 22:11:25

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:11:15', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0ddf7a02-a86f-489d-9b6c-78f487f502be' User entered 'No (N)'	System	01 Oct 2020 22:11:25
	System	01 Oct 2020 22:11:25

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-01T18:11:22', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0ddf7a02-a86f-489d-9b6c-78f487f502be' User entered '01 Oct 2020 18:11'	System	01 Oct 2020 22:11:25
	System	01 Oct 2020 22:11:25

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 4'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:39', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '47bca5ee-99b1-422d-9233-9541a41d6afd' User entered 'None (0)'	System	02 Oct 2020 21:54:59
	System	02 Oct 2020 21:54:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:43', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '47bca5ee-99b1-422d-9233-9541a41d6afd' User entered 'None (0)'	System	02 Oct 2020 21:54:59
	System	02 Oct 2020 21:54:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:45', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '47bca5ee-99b1-422d-9233-9541a41d6afd' User entered 'None (0)'	System	02 Oct 2020 21:54:59
	System	02 Oct 2020 21:54:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:46', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '47bca5ee-99b1-422d-9233-9541a41d6afd' User entered 'None (0)'	System	02 Oct 2020 21:54:59
	System	02 Oct 2020 21:54:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:48', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '47bca5ee-99b1-422d-9233-9541a41d6afd' User entered 'None (0)'	System	02 Oct 2020 21:54:59
	System	02 Oct 2020 21:54:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:50', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '47bca5ee-99b1-422d-9233-9541a41d6afd' User entered 'None (0)'	System	02 Oct 2020 21:54:59
	System	02 Oct 2020 21:54:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:52', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '47bca5ee-99b1-422d-9233-9541a41d6afd' User entered 'No (N)'	System	02 Oct 2020 21:54:59
	System	02 Oct 2020 21:54:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-02T17:54:54', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '47bca5ee-99b1-422d-9233-9541a41d6afd' User entered '02 Oct 2020 17:54'	System	02 Oct 2020 21:54:59
	System	02 Oct 2020 21:54:59

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 5'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5031095e-d8c1-4af6-ad98-bd9dc212cbce' User entered 'None (0)'	System	03 Oct 2020 22:07:04
	System	03 Oct 2020 22:07:04

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:47', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5031095e-d8c1-4af6-ad98-bd9dc212cbce' User entered 'None (0)'	System	03 Oct 2020 22:07:04
	System	03 Oct 2020 22:07:04

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:49', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5031095e-d8c1-4af6-ad98-bd9dc212cbce' User entered 'None (0)'	System	03 Oct 2020 22:07:04
	System	03 Oct 2020 22:07:04

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:51', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5031095e-d8c1-4af6-ad98-bd9dc212cbce' User entered 'None (0)'	System	03 Oct 2020 22:07:04
	System	03 Oct 2020 22:07:04

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:53', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5031095e-d8c1-4af6-ad98-bd9dc212cbce' User entered 'None (0)'	System	03 Oct 2020 22:07:04
	System	03 Oct 2020 22:07:04

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:06:55', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5031095e-d8c1-4af6-ad98-bd9dc212cbce' User entered 'None (0)'	System	03 Oct 2020 22:07:04
	System	03 Oct 2020 22:07:04

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:07:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5031095e-d8c1-4af6-ad98-bd9dc212cbce' User entered 'No (N)'	System	03 Oct 2020 22:07:04
	System	03 Oct 2020 22:07:04

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-03T18:07:02', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5031095e-d8c1-4af6-ad98-bd9dc212cbce' User entered '03 Oct 2020 18:07'	System	03 Oct 2020 22:07:04
	System	03 Oct 2020 22:07:04

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 6'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:42:58', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'cb1cab69-cfdb-40f7-b422-a2d91aedd81f' User entered 'None (0)'	System	04 Oct 2020 21:43:19
	System	04 Oct 2020 21:43:19

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:43:01', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'cb1cab69-cfdb-40f7-b422-a2d91aedd81f' User entered 'None (0)'	System	04 Oct 2020 21:43:19
	System	04 Oct 2020 21:43:19

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:43:03', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'cb1cab69-cfdb-40f7-b422-a2d91aedd81f' User entered 'None (0)'	System	04 Oct 2020 21:43:19
	System	04 Oct 2020 21:43:19

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:43:05', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'cb1cab69-cfdb-40f7-b422-a2d91aedd81f' User entered 'None (0)'	System	04 Oct 2020 21:43:19
	System	04 Oct 2020 21:43:19

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:43:07', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'cb1cab69-cfdb-40f7-b422-a2d91aedd81f' User entered 'None (0)'	System	04 Oct 2020 21:43:19
	System	04 Oct 2020 21:43:19

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:43:09', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'cb1cab69-cfdb-40f7-b422-a2d91aedd81f' User entered 'None (0)'	System	04 Oct 2020 21:43:19
	System	04 Oct 2020 21:43:19

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:43:11', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'cb1cab69-cfdb-40f7-b422-a2d91aedd81f' User entered 'No (N)'	System	04 Oct 2020 21:43:19
	System	04 Oct 2020 21:43:19

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-04T17:43:18', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'cb1cab69-cfdb-40f7-b422-a2d91aedd81f' User entered '04 Oct 2020 17:43'	System	04 Oct 2020 21:43:19
	System	04 Oct 2020 21:43:19

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	29 Sep 2020 14:02:56
User entered 'Day 7'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:50', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0307c7f9-3ab4-41aa-a7bd-c3c7fd5ef055' User entered 'None (0)'	System	05 Oct 2020 21:30:09
	System	05 Oct 2020 21:30:09

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:52', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0307c7f9-3ab4-41aa-a7bd-c3c7fd5ef055' User entered 'None (0)'	System	05 Oct 2020 21:30:09
	System	05 Oct 2020 21:30:09

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:53', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0307c7f9-3ab4-41aa-a7bd-c3c7fd5ef055' User entered 'None (0)'	System	05 Oct 2020 21:30:09
	System	05 Oct 2020 21:30:09

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:55', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0307c7f9-3ab4-41aa-a7bd-c3c7fd5ef055' User entered 'None (0)'	System	05 Oct 2020 21:30:09
	System	05 Oct 2020 21:30:09

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:57', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0307c7f9-3ab4-41aa-a7bd-c3c7fd5ef055' User entered 'None (0)'	System	05 Oct 2020 21:30:09
	System	05 Oct 2020 21:30:09

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:29:59', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0307c7f9-3ab4-41aa-a7bd-c3c7fd5ef055' User entered 'None (0)'	System	05 Oct 2020 21:30:09
	System	05 Oct 2020 21:30:09

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:30:02', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0307c7f9-3ab4-41aa-a7bd-c3c7fd5ef055' User entered 'No (N)'	System	05 Oct 2020 21:30:09
	System	05 Oct 2020 21:30:09

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-05T17:30:07', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '0307c7f9-3ab4-41aa-a7bd-c3c7fd5ef055' User entered '05 Oct 2020 17:30'	System	05 Oct 2020 21:30:09
	System	05 Oct 2020 21:30:09

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:02:56

US3082122

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:02:56

US3082122

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:36:53

US3082122

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:36:53

US3082122

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:36:53

US3082122

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:36:53

US3082122

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:36:57

US3082122

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'I'	System	06 Oct 2020 12:36:57

US3082122

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	Morgan Mathis (b) (4)	13 Oct 2020 13:44:13

US3082122

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '13 Oct 2020'	(b) (4) Morgan Mathis (b) (4)	13 Oct 2020 13:44:13

US3082122

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Morgan Mathis (b) (4)	13 Oct 2020 13:44:13

US3082122

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	Morgan Mathis (b) (4)	13 Oct 2020 13:44:13

US3082122

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	13 Oct 2020 13:47:36

US3082122

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'I'	System	13 Oct 2020 13:47:36

US3082122

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:42

US3082122

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '20 Oct 2020'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:42

US3082122

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:42

US3082122

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	Erin Harrelson (b) (4)	20 Oct 2020 15:58:42

US3082122

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:47

US3082122

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'I'	System	20 Oct 2020 15:58:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:47:35

US3082122

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:47:35

US3082122

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:47:35

US3082122

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'VISIT3'	System	30 Oct 2020 12:47:35

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '08:10'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered '30 Oct 2020 08:10'	System	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '74'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'bpm'	System	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '18'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'breaths/min'	System	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '124'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'mmHg'	System	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '72'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'mmHg'	System	30 Oct 2020 12:48:47

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28

US3082122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28

US3082122

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:48:56

US3082122

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:48:56

US3082122

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:49:19

US3082122

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:49:19

US3082122

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered '08:25'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:49:19

US3082122

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered '30 Oct 2020 08:25'	System	30 Oct 2020 12:49:19

US3082122

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:15:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:49:31

US3082122

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'I'	System	30 Oct 2020 12:49:31

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 64'	System	27 Aug 2020 14:25:11

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-27T13:39:21', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '06b39c08-e5a6-481b-8ba9-7203b83c8314'	System	27 Oct 2020 17:40:06
User entered 'No (N)'	System	27 Oct 2020 17:40:06

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-27T13:39:25', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '06b39c08-e5a6-481b-8ba9-7203b83c8314'	System	27 Oct 2020 17:40:06
User entered 'No (N)'	System	27 Oct 2020 17:40:06

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-10-27T13:39:32', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '06b39c08-e5a6-481b-8ba9-7203b83c8314' User entered '27 Oct 2020 13:39:32'	System	27 Oct 2020 17:40:06
	System	27 Oct 2020 17:40:06

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 14:25:11

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 71'	System	27 Aug 2020 14:25:11

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-11-03T05:45:17', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b7ebc888-34ac-4774-8fbf-6a99f80fc0c4'	System	03 Nov 2020 10:45:33
User entered 'No (N)'	System	03 Nov 2020 10:45:33

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-11-03T05:45:24', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b7ebc888-34ac-4774-8fbf-6a99f80fc0c4'	System	03 Nov 2020 10:45:33
User entered 'No (N)'	System	03 Nov 2020 10:45:33

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-11-03T05:45:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b7ebc888-34ac-4774-8fbf-6a99f80fc0c4' User entered '03 Nov 2020 05:45:30'	System	03 Nov 2020 10:45:33
	System	03 Nov 2020 10:45:33

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 14:25:11

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered 'Day 78'	System	27 Aug 2020 14:25:11

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-11-10T05:34:09', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '601942e7-b776-47ce-9333-56b615e29d1f' User entered 'No (N)'	System	10 Nov 2020 10:34:23
	System	10 Nov 2020 10:34:23

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-11-10T05:34:15', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '601942e7-b776-47ce-9333-56b615e29d1f' User entered 'No (N)'	System	10 Nov 2020 10:34:23
	System	10 Nov 2020 10:34:23

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-11-10T05:34:20', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '601942e7-b776-47ce-9333-56b615e29d1f' User entered '10 Nov 2020 05:34:20'	System	10 Nov 2020 10:34:23
	System	10 Nov 2020 10:34:23

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 14:25:11

US3082122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:41:27
Data entry locked.	System	27 Aug 2020 14:25:11
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 14:25:11

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-11-24T05:43:33', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b2827f33-5783-4324-8853-ff6bcf0e193c'	System	24 Nov 2020 10:43:54
User entered 'No (N)'	System	24 Nov 2020 10:43:54

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-11-24T05:43:39', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b2827f33-5783-4324-8853-ff6bcf0e193c'	System	24 Nov 2020 10:43:54
User entered 'No (N)'	System	24 Nov 2020 10:43:54

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-11-24T05:43:49', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b2827f33-5783-4324-8853-ff6bcf0e193c' User entered '24 Nov 2020 05:43:49'	System	24 Nov 2020 10:43:54
	System	24 Nov 2020 10:43:54

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-11-28T06:09:17', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6bf89740-e50a-469e-a726-648a93a621f1' User entered 'No (N)'	System	28 Nov 2020 11:09:28
	System	28 Nov 2020 11:09:28

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-11-28T06:09:22', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6bf89740-e50a-469e-a726-648a93a621f1' User entered 'No (N)'	System	28 Nov 2020 11:09:28

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-11-28T06:09:26', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6bf89740-e50a-469e-a726-648a93a621f1' User entered '28 Nov 2020 06:09:26'	System	28 Nov 2020 11:09:28
	System	28 Nov 2020 11:09:28

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-12-05T09:33:44', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '4ad41982-722e-4a05-b0e3-0b6210ce4561' User entered 'No (N)'	System	05 Dec 2020 19:16:13
	System	05 Dec 2020 19:16:13

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-12-05T09:33:51', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '4ad41982-722e-4a05-b0e3-0b6210ce4561' User entered 'No (N)'	System	05 Dec 2020 19:16:13
	System	05 Dec 2020 19:16:13

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-12-05T09:33:55', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '4ad41982-722e-4a05-b0e3-0b6210ce4561' User entered '05 Dec 2020 09:33:55'	System	05 Dec 2020 19:16:13
	System	05 Dec 2020 19:16:13

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-12-13T06:14:53', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '81f442dc-5eb4-44aa-9423-a40b639d0698'	System	13 Dec 2020 11:15:07
User entered 'No (N)'	System	13 Dec 2020 11:15:07

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-12-13T06:14:58', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '81f442dc-5eb4-44aa-9423-a40b639d0698' User entered 'No (N)'	System	13 Dec 2020 11:15:07
	System	13 Dec 2020 11:15:07

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-12-13T06:15:04', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '81f442dc-5eb4-44aa-9423-a40b639d0698' User entered '13 Dec 2020 06:15:04'	System	13 Dec 2020 11:15:07
	System	13 Dec 2020 11:15:07

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-12-19T11:02:28', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'e3b219e4-4220-4411-99eb-3de49ecf19f0'	System	19 Dec 2020 16:02:40
User entered 'No (N)'	System	19 Dec 2020 16:02:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-12-19T11:02:33', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'e3b219e4-4220-4411-99eb-3de49ecf19f0'	System	19 Dec 2020 16:02:40
User entered 'No (N)'	System	19 Dec 2020 16:02:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-12-19T11:02:38', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'e3b219e4-4220-4411-99eb-3de49ecf19f0' User entered '19 Dec 2020 11:02:38'	System	19 Dec 2020 16:02:40
	System	19 Dec 2020 16:02:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-12-27T13:34:51', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5723d72e-2721-49ad-82ec-3bfa0c9bab90' User entered 'No (N)'	System	27 Dec 2020 18:35:03
	System	27 Dec 2020 18:35:03

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-12-27T13:34:53', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5723d72e-2721-49ad-82ec-3bfa0c9bab90' User entered 'No (N)'	System	27 Dec 2020 18:35:03
	System	27 Dec 2020 18:35:03

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2020-12-27T13:34:57', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5723d72e-2721-49ad-82ec-3bfa0c9bab90' User entered '27 Dec 2020 13:34:57'	System	27 Dec 2020 18:35:03
	System	27 Dec 2020 18:35:03

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-02T14:53:18', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b9af517a-107e-44b7-a8ae-b4bf48eadfab' User entered 'No (N)'	System	02 Jan 2021 19:53:28
	System	02 Jan 2021 19:53:28

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-02T14:53:20', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b9af517a-107e-44b7-a8ae-b4bf48eadfab' User entered 'No (N)'	System	02 Jan 2021 19:53:28

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-02T14:53:23', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b9af517a-107e-44b7-a8ae-b4bf48eadfab' User entered '02 Jan 2021 14:53:23'	System	02 Jan 2021 19:53:28
	System	02 Jan 2021 19:53:28

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-09T10:09:59', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'a12c56fe-ea39-4cc1-9d37-609bf4e5b17a' User entered 'No (N)'	System	09 Jan 2021 15:10:15
	System	09 Jan 2021 15:10:15

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-09T10:10:09', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'a12c56fe-ea39-4cc1-9d37-609bf4e5b17a' User entered 'No (N)'	System	09 Jan 2021 15:10:15

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-09T10:10:13', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'a12c56fe-ea39-4cc1-9d37-609bf4e5b17a' User entered '09 Jan 2021 10:10:13'	System	09 Jan 2021 15:10:15
	System	09 Jan 2021 15:10:15

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-16T15:45:26', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '53254a66-1f39-46f9-b719-6c2407d61add' User entered 'No (N)'	System	16 Jan 2021 20:45:35
	System	16 Jan 2021 20:45:35

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-16T15:45:28', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '53254a66-1f39-46f9-b719-6c2407d61add' User entered 'No (N)'	System	16 Jan 2021 20:45:35

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-16T15:45:32', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '53254a66-1f39-46f9-b719-6c2407d61add' User entered '16 Jan 2021 15:45:32'	System	16 Jan 2021 20:45:35
	System	16 Jan 2021 20:45:35

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-23T07:34:29', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '68b53042-3311-48da-a471-b812cb6d5e57'	System	23 Jan 2021 12:34:40
User entered 'No (N)'	System	23 Jan 2021 12:34:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-23T07:34:31', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '68b53042-3311-48da-a471-b812cb6d5e57'	System	23 Jan 2021 12:34:40
User entered 'No (N)'	System	23 Jan 2021 12:34:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-23T07:34:36', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '68b53042-3311-48da-a471-b812cb6d5e57'	System	23 Jan 2021 12:34:40
User entered '23 Jan 2021 07:34:36'	System	23 Jan 2021 12:34:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-30T12:39:55', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '71e78053-6821-401c-ab5e-ef237ffa89ce' User entered 'No (N)'	System	30 Jan 2021 17:40:07
	System	30 Jan 2021 17:40:07

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-30T12:39:58', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '71e78053-6821-401c-ab5e-ef237ffa89ce'	System	30 Jan 2021 17:40:07
User entered 'No (N)'	System	30 Jan 2021 17:40:07

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-01-30T12:40:03', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '71e78053-6821-401c-ab5e-ef237ffa89ce' User entered '30 Jan 2021 12:40:03'	System	30 Jan 2021 17:40:07
	System	30 Jan 2021 17:40:07

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-06T12:27:23', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6e9059a9-f73c-4ddb-a472-c73aaa6dbb7c' User entered 'No (N)'	System	06 Feb 2021 17:27:32
	System	06 Feb 2021 17:27:32

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-06T12:27:26', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6e9059a9-f73c-4ddb-a472-c73aaa6dbb7c' User entered 'No (N)'	System	06 Feb 2021 17:27:32
	System	06 Feb 2021 17:27:32

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-06T12:27:29', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '6e9059a9-f73c-4ddb-a472-c73aaa6dbb7c' User entered '06 Feb 2021 12:27:29'	System	06 Feb 2021 17:27:32

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-13T11:20:30', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5e544e5f-838b-45f1-88af-14062f31f6ba' User entered 'No (N)'	System	13 Feb 2021 16:20:38
	System	13 Feb 2021 16:20:38

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-13T11:20:33', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5e544e5f-838b-45f1-88af-14062f31f6ba' User entered 'No (N)'	System	13 Feb 2021 16:20:38
	System	13 Feb 2021 16:20:38

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-13T11:20:36', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '5e544e5f-838b-45f1-88af-14062f31f6ba' User entered '13 Feb 2021 11:20:36'	System	13 Feb 2021 16:20:38
	System	13 Feb 2021 16:20:38

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-20T08:32:28', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b8068544-c9c2-4901-903f-d2321ebbb470' User entered 'No (N)'	System	20 Feb 2021 13:32:38
	System	20 Feb 2021 13:32:38

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-20T08:32:31', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b8068544-c9c2-4901-903f-d2321ebbb470' User entered 'No (N)'	System	20 Feb 2021 13:32:38

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-20T08:32:36', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b8068544-c9c2-4901-903f-d2321ebbb470'	System	20 Feb 2021 13:32:38
User entered '20 Feb 2021 08:32:36'	System	20 Feb 2021 13:32:38

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-27T18:47:07-05:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b0f39a7c-2ee0-49fd-a6a3-e27c2c12062e'	System	27 Feb 2021 23:47:17
User entered 'No (N)'	System	27 Feb 2021 23:47:17

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-27T18:47:10-05:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b0f39a7c-2ee0-49fd-a6a3-e27c2c12062e' User entered 'No (N)'	System	27 Feb 2021 23:47:17

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-27T18:47:14-05:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b0f39a7c-2ee0-49fd-a6a3-e27c2c12062e' User entered '27 Feb 2021 23:47:14'	System	27 Feb 2021 23:47:17
	System	27 Feb 2021 23:47:17

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-03-06T08:51:09-05:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'f55cd6c9-bf44-4475-a793-07640126f11c' User entered 'No (N)'	System	06 Mar 2021 13:51:19
	System	06 Mar 2021 13:51:19

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-03-06T08:51:13-05:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'f55cd6c9-bf44-4475-a793-07640126f11c' User entered 'No (N)'	System	06 Mar 2021 13:51:19
	System	06 Mar 2021 13:51:19

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-03-06T08:51:16-05:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'f55cd6c9-bf44-4475-a793-07640126f11c' User entered '06 Mar 2021 08:51:16'	System	06 Mar 2021 13:51:19
	System	06 Mar 2021 13:51:19

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-03-13T14:09:12-05:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '8f05590b-0044-406d-bc1f-fa157c801069'	System	13 Mar 2021 19:09:20
User entered 'No (N)'	System	13 Mar 2021 19:09:20

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-03-13T14:09:16-05:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '8f05590b-0044-406d-bc1f-fa157c801069' User entered 'No (N)'	System	13 Mar 2021 19:09:20
	System	13 Mar 2021 19:09:20

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-03-13T14:09:18-05:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '8f05590b-0044-406d-bc1f-fa157c801069' User entered '13 Mar 2021 14:09:18'	System	13 Mar 2021 19:09:20
	System	13 Mar 2021 19:09:20

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-03-20T08:22:11-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '48dd6345-62f0-4cc6-a388-19989336691a'	System	20 Mar 2021 12:22:24
User entered 'No (N)'	System	20 Mar 2021 12:22:24

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-03-20T08:22:14-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '48dd6345-62f0-4cc6-a388-19989336691a' User entered 'No (N)'	System	20 Mar 2021 12:22:24
	System	20 Mar 2021 12:22:24

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-03-20T08:22:20-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '48dd6345-62f0-4cc6-a388-19989336691a' User entered '20 Mar 2021 08:22:20'	System	20 Mar 2021 12:22:24
	System	20 Mar 2021 12:22:24

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-03-28T19:51:37-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b0cad1d4-59f2-44e3-abf3-7fc5b7e67a5c'	System	28 Mar 2021 23:51:45
User entered 'No (N)'	System	28 Mar 2021 23:51:45

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-03-28T19:51:40-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b0cad1d4-59f2-44e3-abf3-7fc5b7e67a5c'	System	28 Mar 2021 23:51:45
User entered 'No (N)'	System	28 Mar 2021 23:51:45

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-03-28T19:51:43-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'b0cad1d4-59f2-44e3-abf3-7fc5b7e67a5c' User entered '28 Mar 2021 19:51:43'	System	28 Mar 2021 23:51:45
	System	28 Mar 2021 23:51:45

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-04-03T08:18:21-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd299158c-3a84-4d43-8afe-0a565f9bb9c8' User entered 'No (N)'	System	03 Apr 2021 12:18:28
	System	03 Apr 2021 12:18:28

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-04-03T08:18:24-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd299158c-3a84-4d43-8afe-0a565f9bb9c8'	System	03 Apr 2021 12:18:28
User entered 'No (N)'	System	03 Apr 2021 12:18:28

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-04-03T08:18:26-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'd299158c-3a84-4d43-8afe-0a565f9bb9c8'	System	03 Apr 2021 12:18:28
User entered '03 Apr 2021 08:18:26'	System	03 Apr 2021 12:18:28

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-04-10T14:15:56-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '81a0f425-8c88-41db-aff7-186f59b4dfab' User entered 'No (N)'	System	10 Apr 2021 18:16:08
	System	10 Apr 2021 18:16:08

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-04-10T14:15:59-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '81a0f425-8c88-41db-aff7-186f59b4dfab' User entered 'No (N)'	System	10 Apr 2021 18:16:08

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-04-10T14:16:02-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '81a0f425-8c88-41db-aff7-186f59b4dfab' User entered '10 Apr 2021 14:16:02'	System	10 Apr 2021 18:16:08
	System	10 Apr 2021 18:16:08

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-04-17T10:33:11-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '771c972b-64cc-43b3-b48a-8c3c9eb7c233'	System	17 Apr 2021 14:33:21
User entered 'No (N)'	System	17 Apr 2021 14:33:21

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-04-17T10:33:15-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '771c972b-64cc-43b3-b48a-8c3c9eb7c233'	System	17 Apr 2021 14:33:21
User entered 'No (N)'	System	17 Apr 2021 14:33:21

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-04-17T10:33:18-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '771c972b-64cc-43b3-b48a-8c3c9eb7c233'	System	17 Apr 2021 14:33:21
User entered '17 Apr 2021 10:33:18'	System	17 Apr 2021 14:33:21

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-04-24T10:27:18-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '47c058ea-5a45-4bac-ae7a-dfd86ca11d32'	System	24 Apr 2021 14:27:27
User entered 'No (N)'	System	24 Apr 2021 14:27:27

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-04-24T10:27:20-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '47c058ea-5a45-4bac-ae7a-dfd86ca11d32'	System	24 Apr 2021 14:27:27
User entered 'No (N)'	System	24 Apr 2021 14:27:27

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-04-24T10:27:23-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '47c058ea-5a45-4bac-ae7a-dfd86ca11d32'	System	24 Apr 2021 14:27:27
User entered '24 Apr 2021 10:27:23'	System	24 Apr 2021 14:27:27

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-05-01T17:38:53-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '14bf6934-bd41-4825-b25c-30d2a3adbf7d'	System	01 May 2021 21:39:01
User entered 'No (N)'	System	01 May 2021 21:39:01

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

Have you been exposed to someone with 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 (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-05-01T17:38:56-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '14bf6934-bd41-4825-b25c-30d2a3adbf7d'	System	01 May 2021 21:39:01
User entered 'No (N)'	System	01 May 2021 21:39:01

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-05-01T17:38:59-04:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: '14bf6934-bd41-4825-b25c-30d2a3adbf7d'	System	01 May 2021 21:39:01
User entered '01 May 2021 17:38:59'	System	01 May 2021 21:39:01

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 18:42:40

US3082122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:42:40
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 18:42:40

US3082122

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:05:19

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 00:12:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-27T18:47:17-05:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'aea834c5-f3f5-4700-aed0-139c66419c1a'	System	27 Feb 2021 23:47:25
User entered 'No (N)'	System	27 Feb 2021 23:47:25

US3082122

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:05:19

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 00:12:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12627C50-6508-46BD-8522-E4D1F33AD01B)', Time: '2021-02-27T18:47:21-05:00', User OID: 'PatientReportedOutcome (US3082122)', ODM File OID: 'aea834c5-f3f5-4700-aed0-139c66419c1a' User entered '27 Feb 2021 23:47:21'	System	27 Feb 2021 23:47:25
	System	27 Feb 2021 23:47:25

US3082122

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	24 Nov 2020 16:14:07

US3082122

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '24 Nov 2020'	Erin Harrelson (b) (4)	24 Nov 2020 16:14:07

US3082122

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4)	24 Nov 2020 16:14:07

US3082122

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	Erin Harrelson (b) (4)	24 Nov 2020 16:14:07

US3082122

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	24 Nov 2020 16:14:11

US3082122

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:25:28
User entered 'I'	System	24 Nov 2020 16:14:11

US3082122

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	28 Dec 2020 15:38:45

US3082122

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '28 Dec 2020'	Erin Harrelson (b) (4)	28 Dec 2020 15:38:45

US3082122

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4)	28 Dec 2020 15:38:45

US3082122

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	Erin Harrelson (b) (4)	28 Dec 2020 15:38:45

US3082122

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	28 Dec 2020 15:38:48

US3082122

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User entered 'I'	System	28 Dec 2020 15:38:48

US3082122

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:56:34

US3082122

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:56:34

US3082122

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:56:34

US3082122

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:56:34

US3082122

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:56:38

US3082122

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User entered 'I'	System	29 Jan 2021 17:56:38

US3082122

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Yes (Y)'	Angie Northcott (b) (4)	26 Feb 2021 14:20:36

US3082122

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '26 Feb 2021'	(b) (4) Angie Northcott (b) (4)	26 Feb 2021 14:20:36

US3082122

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Angie Northcott (b) (4)	26 Feb 2021 14:20:36

US3082122

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Angie Northcott (b) (4)	26 Feb 2021 14:20:36

US3082122

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Yes (Y)'	(b) (4) Angie Northcott (b) (4)	26 Feb 2021 14:20:27

US3082122

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:38:07
User entered 'I'	System	26 Feb 2021 14:20:27

US3082122

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:21:07

US3082122

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:21:07

US3082122

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[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 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:21:07

US3082122

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User entered 'VISIT4'	System	26 Mar 2021 15:21:07

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered 'No (N)'	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User entered empty.	System	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User entered empty.	System	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User entered empty.	System	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User entered empty.	System	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User entered empty.	System	30 Mar 2021 19:42:00

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28

US3082122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28

US3082122

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:21:15

US3082122

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:21:15

US3082122

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:21:23

US3082122

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:21:23

US3082122

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:21:23

US3082122

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User entered empty.	System	26 Mar 2021 15:21:23

US3082122

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:21:40

US3082122

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:56:28
User entered 'I'	System	26 Mar 2021 15:21:40

US3082122

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

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:01:59

US3082122

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

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:01:59

US3082122

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

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:01:59

US3082122

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

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 14:01:59

US3082122

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:19

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:15:00
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 17:15:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:28

US3082122

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:19

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:15:00
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:43:12

US3082122

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:19

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:28

US3082122

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:19

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
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)	15 Apr 2021 19:37:04
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).	(b) (4), (b) (6)	12 Apr 2021 17:15:30
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	12 Apr 2021 17:15:00
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)	09 Apr 2021 19:37:44
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:43:12

US3082122

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:19

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:28

US3082122

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:19

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:28

US3082122

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:19

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:28

US3082122

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:19

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:28

US3082122

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:19

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:28

US3082122

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:19

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '1'	System	22 Jan 2021 14:02:28

US3082122

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:19

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'I'	System	22 Jan 2021 14:02:28

US3082122

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '63.5' in	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '118.6' lb	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '20.72274'	System	22 Jan 2021 14:06:02
DataPoint set to visible.	System	22 Jan 2021 14:02:28

US3082122

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '63.5' in	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '118.6' lb	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '20.72274'	System	22 Jan 2021 14:06:02
DataPoint set to visible.	System	22 Jan 2021 14:02:28

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
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	22 Jan 2021 14:07:25
User entered 'Yes (Y)' reason for change: Data Entry Error	System	22 Jan 2021 14:07:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 14:06:02
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '22 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 14:07:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '08:06' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 14:07:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '22 Jan 2021 08:06'	System	22 Jan 2021 14:07:25
User entered empty.	System	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 14:07:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 14:33:24
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 14:07:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'FOREHEAD' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 14:33:24
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '81' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 14:07:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'bpm'	System	22 Jan 2021 14:07:25
User entered empty.	System	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 14:07:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'breaths/min'	System	22 Jan 2021 14:07:25
User entered empty.	System	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '134' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:07:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'mmHg'	System	22 Jan 2021 14:07:25
User entered empty.	System	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 14:07:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'mmHg'	System	22 Jan 2021 14:07:25
User entered empty.	System	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '63.5' in	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '118.6' lb	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '20.72274'	System	22 Jan 2021 14:06:02
DataPoint set to visible.	System	22 Jan 2021 14:02:28

US3082122

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Jan 2021 14:33:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 14:33:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	22 Jan 2021 14:33:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Jan 2021 14:06:02
User entered empty.	System	22 Jan 2021 14:06:02
	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '22 Jan 2021' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 14:33:24
User entered empty.	Morgan Mathis (b) (4)	22 Jan 2021 14:06:02
	(b) (4), (b) (6)	

US3082122

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '09:28' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 14:33:24
User entered empty.	Morgan Mathis (b) (4)	22 Jan 2021 14:06:02
	(b) (4), (b) (6)	

US3082122

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '22 Jan 2021 09:28'	System	22 Jan 2021 14:33:24
User entered empty.	System	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '97.2' F reason for change: Data Entry Error	(b) (4)	22 Jan 2021 14:33:24
User entered empty.	Morgan Mathis (b) (4)	22 Jan 2021 14:06:02
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 14:33:24
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'FOREHEAD' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 14:33:24
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '74' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 14:33:24
User entered empty.	Morgan Mathis (b) (4)	22 Jan 2021 14:06:02
	(b) (4)	
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'bpm'	System	22 Jan 2021 14:33:24
User entered empty.	System	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '16' reason for change: Data Entry Error	Morgan Mathis (b) (4)	22 Jan 2021 14:33:24
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'breaths/min'	System	22 Jan 2021 14:33:24
User entered empty.	System	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '124' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 14:33:24
User entered empty.	Morgan Mathis (b) (4)	22 Jan 2021 14:06:02
	(b) (4)	
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'mmHg'	System	22 Jan 2021 14:33:24
User entered empty.	System	22 Jan 2021 14:06:02

US3082122

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '74' reason for change: Data Entry Error	Morgan Mathis (b) (4)	22 Jan 2021 14:33:24
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:06:02

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'mmHg'	System	22 Jan 2021 14:33:24
User entered empty.	System	22 Jan 2021 14:06:02

US3082122

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:03:42

US3082122

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:03:42

US3082122

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4) System	22 Jan 2021 15:21:26
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	22 Jan 2021 15:21:26
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	22 Jan 2021 14:03:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 14:03:30

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:03:30

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

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)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:03:30

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'mRNA-1273'	System	22 Jan 2021 14:03:30
DataPoint set to visible.	System	22 Jan 2021 14:02:28

US3082122

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:03:30

US3082122

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '08:58' reason for change: Data Entry Error	Ayssa Valente (b) (4)	22 Jan 2021 15:21:26
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:03:30

US3082122

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '22 Jan 2021 08:58'	System	22 Jan 2021 15:21:26
User entered empty.	System	22 Jan 2021 14:03:30

US3082122

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 15:21:26
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:03:30

US3082122

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'ONCE'	System	22 Jan 2021 14:03:30

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 14:03:30

US3082122

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:41

US3082122

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:41

US3082122

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '08:35'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:41

US3082122

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '22 Jan 2021 08:35'	System	22 Jan 2021 14:02:41

US3082122

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:55

US3082122

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:55

US3082122

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:05:19

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '08:33'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:02:55

US3082122

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:05:19

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '22 Jan 2021 08:33'	System	22 Jan 2021 14:02:55

US3082122

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

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:03:00

US3082122

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

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'I'	System	22 Jan 2021 14:03:00

US3082122

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:56:19

US3082122

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:56:19

US3082122

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:56:19

US3082122

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 17:56:19

US3082122

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:56:23

US3082122

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'I'	System	29 Jan 2021 17:56:23

US3082122

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '1'	System	29 Jan 2021 17:56:23
DataPoint set to visible.	System	29 Jan 2021 17:56:23

US3082122

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:28:51

US3082122

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:28:51

US3082122

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:28:51

US3082122

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'OLD29'	System	19 Feb 2021 13:28:51

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '08:05'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '19 Feb 2021 08:05'	System	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '78'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'bpm'	System	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'breaths/min'	System	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '119'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'mmHg'	System	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '71'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'mmHg'	System	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '08:51'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '19 Feb 2021 08:51'	System	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 13:55:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Feb 2021 13:55:36
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 13:55:36
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 13:33:34
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Feb 2021 13:55:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Feb 2021 13:55:36
User entered '71' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 13:55:36
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 13:33:34
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'bpm'	System	19 Feb 2021 13:55:36
User entered empty.	System	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Feb 2021 13:55:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Feb 2021 13:55:36
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 13:55:36
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 13:33:34
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'breaths/min'	System	19 Feb 2021 13:55:36
User entered empty.	System	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Feb 2021 13:55:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Feb 2021 13:55:36
User entered '117' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 13:55:36
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 13:33:34
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'mmHg'	System	19 Feb 2021 13:55:36
User entered empty.	System	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Feb 2021 13:55:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Feb 2021 13:55:36
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 13:55:36
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 13:33:34
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'mmHg'	System	19 Feb 2021 13:55:36
User entered empty.	System	19 Feb 2021 13:33:34

US3082122

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:29:18

US3082122

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 13:29:18

US3082122

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:29:08

US3082122

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:29:08

US3082122

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

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)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:29:08

US3082122

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'mRNA-1273'	System	19 Feb 2021 13:29:08
DataPoint set to visible.	System	29 Jan 2021 17:56:23

US3082122

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:29:08

US3082122

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered '08:21'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:29:08

US3082122

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '19 Feb 2021 08:21'	System	19 Feb 2021 13:29:08

US3082122

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:29:08

US3082122

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'ONCE'	System	19 Feb 2021 13:29:08

US3082122

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 13:29:08

US3082122

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:29:13

US3082122

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'I'	System	19 Feb 2021 13:29:13

US3082122

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Yes (Y)'	Angie Northcott (b) (4)	26 Feb 2021 14:20:47

US3082122

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '26 Feb 2021'	Angie Northcott (b) (4)	26 Feb 2021 14:20:47

US3082122

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Contact Made (CONTACT MADE)'	Angie Northcott (b) (4)	26 Feb 2021 14:20:47

US3082122

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	Angie Northcott (b) (4)	26 Feb 2021 14:20:47

US3082122

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Yes (Y)'	Angie Northcott (b) (4)	26 Feb 2021 14:20:52

US3082122

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'I'	System	26 Feb 2021 14:20:52

US3082122

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:34:04

US3082122

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:34:04

US3082122

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:34:04

US3082122

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'OLD57'	System	26 Mar 2021 13:34:04

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '08:12'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '26 Mar 2021 08:12'	System	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '74'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'bpm'	System	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '15'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'breaths/min'	System	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '134'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'mmHg'	System	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '73'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered 'mmHg'	System	26 Mar 2021 13:35:32

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46

US3082122

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:19

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46

US3082122

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:35:50

US3082122

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:35:50

US3082122

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:36:37

US3082122

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:36:37

US3082122

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User entered '08:24'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:36:37

US3082122

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:16:46
User entered '26 Mar 2021 08:24'	System	26 Mar 2021 13:36:37

US3082122

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:05:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:23:18
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
Signature has been broken.	Ayssa Valente (b) (4)	26 Feb 2021 19:37:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	26 Feb 2021 19:37:56
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'No (N)'	Brandy Lowman (b) (4)	29 Sep 2020 12:22:48

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:54
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:22:45
Un-reviewed for Safety.		06 Apr 2021 14:22:42
Reviewed for Safety.		29 Mar 2021 15:04:22
User entered 'USA-US114-2021-mRNA-1273-P301000007'	System	29 Mar 2021 15:04:11
User entered 'New'	(b) (4), (b) (6)	29 Mar 2021 15:04:11

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 19:42:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 19:42:54
Data point term sent to Coder	System	26 Feb 2021 19:42:20
User entered 'kidney stones'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'No (N)'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'No (N)'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User closed query 'PV Query: With event onset being 17 Feb 2021, please clarify what symptoms subject was experiencing from 17 Feb 2021-26 Feb 2021. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:22:22
Query 'PV Query: With event onset being 17 Feb 2021, please clarify what symptoms subject was experiencing from 17 Feb 2021-26 Feb 2021. ' answered with 'Patient was experiencing left lower quadrant abdominal pain. Patient denied any nausea, vomiting, fever/chills, and painful urination. ' (Site from Safety).	Erin Harrelson (b) (4) (b) (4)	05 Apr 2021 14:27:39
User opened query 'PV Query: With event onset being 17 Feb 2021, please clarify what symptoms subject was experiencing from 17 Feb 2021-26 Feb 2021. ' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:11:08
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered '17 Feb 2021'	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) ((b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:54
Signature has been broken.	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User entered 'No (N)' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 19:41:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 19:41:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:48
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 19:41:39
User entered empty.	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) ((b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:54
Signature has been broken.	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User entered '26 Feb 2021' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered empty.	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:54
Signature has been broken.	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User entered 'Yes (Y)' reason for change: New Information	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '0'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '0'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:54
Signature has been broken.	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User entered '1' reason for change: New Information	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered '0'	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:54
Signature has been broken.	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User entered '26 Feb 2021' reason for change: New Information	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered empty.	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:54
Signature has been broken.	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User entered '27 Feb 2021' reason for change: New Information	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered empty.	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:54
Signature has been broken.	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User entered 'No (N)' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered empty.	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '0'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

US3082122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '0'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '0'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Not Related (NOT RELATED)'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Not Related (NOT RELATED)'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User closed query ' Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit. Review and update as appropriate as per CCGs.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:30:34
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
Query ' Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit. Review and update as appropriate as per CCGs.'	Ayssa Valente (b) (4)	05 Mar 2021 13:32:37
answered with 'updated to None' (Site from DM).	(b) (4)	
User entered 'None (NONE)' reason for change:	Ayssa Valente (b) (4)	05 Mar 2021 13:32:31
Data Entry Error	(b) (4)	
User opened query ' Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 visit. Review and update as appropriate as per CCGs.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 13:03:01
User entered 'Not Applicable (NOT APPLICABLE)'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

None

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:54
User closed query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #9, 10, 11 and 12 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 02:27:51
Query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #9, 10, 11 and 12 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	10 Mar 2021 12:51:14
Signature has been broken.	Erin Harrelson (b) (4) (b) (4)	10 Mar 2021 12:51:07
User entered '0' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	10 Mar 2021 12:51:07
User opened query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #9, 10, 11 and 12 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 12:35:12
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered '1'	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:54
Signature has been broken.	Erin Harrelson (b) (4) (b) (4)	10 Mar 2021 12:51:07
User entered '1' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	10 Mar 2021 12:51:07
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered '0'	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 03:43:54
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)	06 Apr 2021 14:22:35
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)	06 Apr 2021 14:22:31
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 laboratory results listed in medical records from hospitalization. Subject has an ECG which was normal and a Cat Scan of Abdomen and Pelvis with IV contrast only. The CT revealed no acute abnormality but the patient's symptoms were suggested of renal colic. Physician states that she most likely already passed the stone and was having residual spasm. ' (Site from Safety).	Megan Marles (b) (4)	05 Apr 2021 17:48:07
User entered '0' reason for change: Data Entry Error	(b) (4)	05 Apr 2021 17:46:43
Signature has been broken.	Megan Marles (b) (4)	05 Apr 2021 17:45:14
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Megan Marles (b) (4)	05 Apr 2021 17:45:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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 'Patient was not tested for COVID-19' (Site from Safety).	Erin Harrelson (b) (4) (b) (4)	05 Apr 2021 14:30:07
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) (b) (4), (b) (6)	05 Apr 2021 13:11:33
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) (b) (4), (b) (6)	05 Apr 2021 13:11:23
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered '0'	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:54
Signature has been broken.	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	26 Mar 2021 18:22:35
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 03:43:54
User closed query 'PV Query: Please provide dates of ECG and CAT scan. If unknown, please indicate so. (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 00:58:35
Query 'PV Query: Please provide dates of ECG and CAT scan. If unknown, please indicate so. ' answered with 'The ECG and CAT scan were performed in hospital on 26Feb2021. ' (Site from Safety).	Megan Marles (b) (4)	12 Apr 2021 19:32:26
	(b) (4)	
User opened query 'PV Query: Please provide dates of ECG and CAT scan. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:33:28
Signature has been broken.	Megan Marles (b) (4)	26 Mar 2021 18:22:35
	(b) (4)	
User entered 'The subject reported kidney stones which required a trip to the emergency room on 26feb2021. The subject spoke to site while in emergency room. The subject was admitted to hospital from emergency department and was discharged on 27feb2021. The subject was treated for pain with IV toradol, IV fluids, and flomax. Pt was pain free at midnight and was discharged. Patient reported resolution of symptoms when on site on 26Mar2021. The site was not aware of hospital admission until patient reported it while on site for office visit on 26Mar2021.' reason for change: New Information	Megan Marles (b) (4)	26 Mar 2021 18:22:35
	(b) (4)	
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
User entered 'Patient reported severe pain that they went to the emergency room for. Diagnosed with kidney stones'	Ayssa Valente (b) (4)	26 Feb 2021 19:41:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Mar 2021 18:22:35
User entered '0'	System	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 19:41:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 18:22:35

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:05:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:23:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'Yes (Y)'	(b) (4) Morgan Mathis (b) (4)	27 Aug 2020 14:59:22

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Sep 2020 13:30:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 13:30:45
Data point term sent to Coder Coding entries removed.	System Erin Harrelson (b) (4)	21 Sep 2020 13:30:23 21 Sep 2020 13:29:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:08
Data point term sent to Coder User entered 'Aspirin'	System Morgan Mathis (b) (4)	27 Aug 2020 15:02:49 27 Aug 2020 15:01:55

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 05:01:11
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'Prophylaxis has been recorded as yes. ' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:30:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:29:57
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Sep 2020 12:06:48
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:01:55

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User closed query 'Per CDM: Please record type of supplement as appropriate (like nutritional supplement, Potassium supplement, etc.).' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 05:01:13
Query 'Per CDM: Please record type of supplement as appropriate (like nutritional supplement, Potassium supplement, etc.).' answered with 'Indication has been updated to cardiac preventative.' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:30:27
User entered 'Cardiac Preventative' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:29:57
User opened query 'Per CDM: Please record type of supplement as appropriate (like nutritional supplement, Potassium supplement, etc.).' (Site from DM).	(b) (4), (b) (6)	19 Sep 2020 12:07:53
User entered 'Supplement'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:01:55

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered '81'	Morgan Mathis (b) (4)	27 Aug 2020 15:01:55
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'mg (mg)'	Morgan Mathis (b) (4)	27 Aug 2020 15:01:55
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 15:01:55
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'once daily (QD)'	Morgan Mathis (b) (4)	27 Aug 2020 15:01:55
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:01:55

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Oral (ORAL)'	Morgan Mathis (b) (4)	27 Aug 2020 15:01:55
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:01:55

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'UN UNK 2016'	Morgan Mathis (b) (4)	27 Aug 2020 15:01:55
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered '0'	Morgan Mathis (b) (4)	27 Aug 2020 15:01:55
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Yes (Y)'	Morgan Mathis (b) (4)	27 Aug 2020 15:01:55
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 15:01:55
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 15:01:55
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:01:55

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:01:55

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:01:55

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Sep 2020 13:31:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 13:31:47
Data point term sent to Coder	System	21 Sep 2020 13:31:24
Coding entries removed.	Erin Harrelson (b) (4)	21 Sep 2020 13:30:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:08
Data point term sent to Coder	System	27 Aug 2020 15:02:50
User entered 'Vitamin D'	Morgan Mathis (b) (4)	27 Aug 2020 15:02:44

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 05:01:23
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'Prophylaxis has been updated to yes. ' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:31:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:30:52
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Sep 2020 12:07:02
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:02:44

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User closed query 'Per CDM: Please record type of supplement as appropriate (like nutritional supplement, Potassium supplement, etc.).' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 05:01:26
Query 'Per CDM: Please record type of supplement as appropriate (like nutritional supplement, Potassium supplement, etc.).' answered with 'Type of supplement has been updated. ' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:31:20
User entered 'NUTRITIONAL SUPPLEMENT' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:30:52
User opened query 'Per CDM: Please record type of supplement as appropriate (like nutritional supplement, Potassium supplement, etc.).' (Site from DM).	(b) (4), (b) (6)	19 Sep 2020 12:07:41
User entered 'Supplement'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:02:44

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered '2000'	Morgan Mathis (b) (4)	27 Aug 2020 15:02:44
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update (eg, iu) as applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 10:47:29
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update (eg, iu) as applicable. ' answered with 'Dosage unit has been updated. ' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:32:31
User entered 'IU (IU)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:31:58
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update (eg, iu) as applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 05:31:58
User entered 'mg (mg)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:02:44

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:02:44

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'once daily (QD)'	Morgan Mathis (b) (4)	27 Aug 2020 15:02:44
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:02:44

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Oral (ORAL)'	Morgan Mathis (b) (4)	27 Aug 2020 15:02:44
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:02:44

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'UN UNK 2010'	Morgan Mathis (b) (4)	27 Aug 2020 15:02:44
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered '0'	Morgan Mathis (b) (4)	27 Aug 2020 15:02:44
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Yes (Y)'	Morgan Mathis (b) (4)	27 Aug 2020 15:02:44
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 15:02:44
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:02:44

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:02:44

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:02:44

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:02:44

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Sep 2020 13:34:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 13:34:49
Data point term sent to Coder	System	21 Sep 2020 13:33:30
Coding entries removed.	Erin Harrelson (b) (4)	21 Sep 2020 13:32:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 19:23:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:11
Data point term sent to Coder	System	27 Aug 2020 15:03:50
User entered 'Magnesium'	Morgan Mathis (b) (4)	27 Aug 2020 15:03:27

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 05:01:39
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'Prophylaxis has been updated to yes. ' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:33:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:32:51
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Sep 2020 12:07:13
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:03:27

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User closed query 'Per CDM: Please record type of supplement as appropriate (like nutritional supplement, Potassium supplement, etc.).' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 05:01:42
Query 'Per CDM: Please record type of supplement as appropriate (like nutritional supplement, Potassium supplement, etc.).' answered with 'Type of supplement has been recorded. ' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:33:12
User entered 'NUTRITIONAL SUPPLEMENT' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:32:51
User opened query 'Per CDM: Please record type of supplement as appropriate (like nutritional supplement, Potassium supplement, etc.).' (Site from DM).	(b) (4), (b) (6)	19 Sep 2020 12:07:28
User entered 'Supplement'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:03:27

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered '500'	Morgan Mathis (b) (4)	27 Aug 2020 15:03:27
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'mg (mg)'	Morgan Mathis (b) (4)	27 Aug 2020 15:03:27
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:03:27

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'once daily (QD)'	Morgan Mathis (b) (4)	27 Aug 2020 15:03:27
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:03:27

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Oral (ORAL)'	Morgan Mathis (b) (4)	27 Aug 2020 15:03:27
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:03:27

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'UN UNK 2010'	Morgan Mathis (b) (4)	27 Aug 2020 15:03:27
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered '0'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:03:27

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:03:27

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 15:03:27
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 15:03:27
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:03:27

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 15:03:27

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:03:27

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN, PRODUCTSYNONYM: IMITREX [SUMATRIPTAN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 19:23:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:23:56
Data point term sent to Coder	System	27 Aug 2020 15:04:51
User entered 'Imitrex'	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Migraines'	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered '50'	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'mg (mg)'	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'as needed (PRN)'	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:04:18

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Oral (ORAL)'	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'UN UNK 2007'	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered '0'	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Yes (Y)'	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 15:04:18
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:04:18

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:04:18

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:04:18

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: DECONGESTANTS AND ANTIALLERGICS, ATC: OTHER ANTIALLERGICS, PRODUCT: KETOTIFEN FUMARATE, PRODUCTSYNONYM: ALAWAY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Aug 2020 19:48:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:48:22
Data point term sent to Coder	System	27 Aug 2020 15:06:53
User entered 'Alaway'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:06:43

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:06:43

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 06:01:38
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Medical condition has been recorded in medical history. ' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:34:14
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 05:32:24
User entered 'Seasonal allergy eye drops'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:06:43

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered '1'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:06:43

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Other (OTHER)'	Morgan Mathis (b) (4)	27 Aug 2020 15:06:43
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'drop per eye'	Morgan Mathis (b) (4)	27 Aug 2020 15:06:43
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'as needed (PRN)'	Morgan Mathis (b) (4)	27 Aug 2020 15:06:43
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:06:43

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Other (OTHER)'	Morgan Mathis (b) (4)	27 Aug 2020 15:06:43
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'ophthalmic'	Morgan Mathis (b) (4)	27 Aug 2020 15:06:43
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'UN UNK 2007'	Morgan Mathis (b) (4)	27 Aug 2020 15:06:43
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered '0'	Morgan Mathis (b) (4)	27 Aug 2020 15:06:43
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Yes (Y)'	Morgan Mathis (b) (4)	27 Aug 2020 15:06:43
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 15:06:43
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 15:06:43
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:06:43

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:06:43

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:06:43

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE, PRODUCTSYNONYM: EPIPEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 14:13:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 14:13:46
Data point term sent to Coder	System	27 Aug 2020 15:07:54
User entered 'Epipen'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:07:49

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:07:49

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 06:02:12
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Medical condition has been recorded in medical history. ' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	21 Sep 2020 13:28:09
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 05:32:56
User entered 'Banana allergy and shell fish allergy (never been used to date)'	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:07:49

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered '0.3'	Morgan Mathis (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'mL (mL)'	Morgan Mathis (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:07:49

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'as needed (PRN)'	Morgan Mathis (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Morgan Mathis (b) (4) (b) (4)	27 Aug 2020 15:07:49

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Morgan Mathis (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

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

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'UN UNK 2000'	Morgan Mathis (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered '0'	Morgan Mathis (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'Yes (Y)'	Morgan Mathis (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered empty.	Morgan Mathis (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
	(b) (4)	
User entered 'No (N)'	Morgan Mathis (b) (4)	27 Aug 2020 15:07:49
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:07:49

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:07:49

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:07:49

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 15:58:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 15:58:38
Data point term sent to Coder	System	20 Oct 2020 15:57:48
User entered 'INFLUENZA VACCINE'	Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'Yes (Y)'	(b) (4) Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'PROPHYLAXIS'	(b) (4) Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered '0.5'	Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'mL (mL)'	(b) (4) Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'once (ONCE)'	(b) (4) Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered empty.	Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered '16 Oct 2020'	(b) (4) Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered '0'	Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'No (N)'	Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered '16 Oct 2020'	Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:14:41
User entered 'No (N)'	(b) (4) Erin Harrelson (b) (4)	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User entered empty.	System	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User entered empty.	System	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:47
User entered empty.	System	20 Oct 2020 15:57:38

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 17:20:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 17:20:43
Data point term sent to Coder	System	02 Mar 2021 17:05:14
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:04:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:04:51
User entered 'sumatriptan' reason for change: Data Entry Error	Ayssa Valente (b) (4)	02 Mar 2021 17:04:51
Data point term sent to Coder	System	02 Mar 2021 17:04:10
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
Data point term sent to Coder	System	20 Oct 2020 16:02:58
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 16:02:41
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4)	20 Oct 2020 16:02:41
Data point term sent to Coder	System	20 Oct 2020 15:58:51
User entered 'DOXYCYCLINE'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:04:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:04:51
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	02 Mar 2021 17:04:51
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 16:02:41
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4)	20 Oct 2020 16:02:41
	(b) (4)	
User entered 'No (N)'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:04:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:04:51
User entered 'migraines' reason for change: Data Entry Error	Ayssa Valente (b) (4)	02 Mar 2021 17:04:51
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 16:02:41
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4)	20 Oct 2020 16:02:41
	(b) (4)	
User entered 'BASAL CELL CARCINOMA + CYST REMOVAL'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:04:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:04:51
User entered '100' reason for change: Data Entry Error	Ayssa Valente (b) (4)	02 Mar 2021 17:04:51
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 16:02:41
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4)	20 Oct 2020 16:02:41
	(b) (4)	
User entered '100'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:04:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:04:51
User entered 'mg (mg)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	02 Mar 2021 17:04:51
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 16:02:41
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4)	20 Oct 2020 16:02:41
	(b) (4)	
User entered 'mg (mg)'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User entered empty.	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:04:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:04:51
User entered 'as needed (PRN)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	02 Mar 2021 17:04:51
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 16:02:41
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4)	20 Oct 2020 16:02:41
	(b) (4)	
User entered 'twice daily (BID)'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User entered empty.	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:04:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:04:51
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	02 Mar 2021 17:04:51
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 16:02:41
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4)	20 Oct 2020 16:02:41
	(b) (4)	
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User entered empty.	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	02 Mar 2021 17:04:51
User entered 'UN UNK 2007' reason for change: Data Entry Error	Ayssa Valente (b) (4)	02 Mar 2021 17:04:51
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	20 Oct 2020 16:02:41
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4)	20 Oct 2020 16:02:41
User entered '19 Oct 2020'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User entered '0'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:04:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:04:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	02 Mar 2021 17:04:51
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 16:02:41
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4)	20 Oct 2020 16:02:41
	(b) (4)	
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User entered empty.	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:04:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:04:51
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	02 Mar 2021 17:04:51
	(b) (4)	
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 16:02:41
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4)	20 Oct 2020 16:02:41
	(b) (4)	
User entered 'No (N)'	Erin Harrelson (b) (4)	20 Oct 2020 15:58:29
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
User entered empty.	System	20 Oct 2020 16:02:41
User entered '2'	System	20 Oct 2020 15:58:29

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
User entered empty.	System	20 Oct 2020 16:02:41
User entered '1'	System	20 Oct 2020 15:58:29

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	02 Mar 2021 17:04:05
DataPoint inactivated with code reason code Data not required.	Erin Harrelson (b) (4)	20 Oct 2020 16:02:53
User entered empty.	System	20 Oct 2020 16:02:41
User entered '804 (804)'	System	20 Oct 2020 15:58:29

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 17:06:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 17:06:43
Data point term sent to Coder	System	02 Mar 2021 17:06:15
User entered 'morphine'	Ayssa Valente (b) (4) (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'No (N)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'kidney stone'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '4'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'mg (mg)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'once (ONCE)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '26 Feb 2021'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '0'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'No (N)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '26 Feb 2021'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'No (N)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User entered empty.	System	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User entered empty.	System	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:54
User entered empty.	System	02 Mar 2021 17:05:32

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:05:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:05:55
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
Data point term sent to Coder	System	02 Mar 2021 17:07:16
User entered 'ondansetron'	Ayssa Valente (b) (4) (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'No (N)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'kidney stone'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '8'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'mg (mg)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'as needed (PRN)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Oral (ORAL)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '26 Feb 2021'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '0'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:03
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	05 Apr 2021 12:31:23
Signature has been broken.	Erin Harrelson (b) (4) (b) (4)	05 Apr 2021 12:31:09
User entered 'No (N)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	05 Apr 2021 12:31:09
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:32:48
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered 'Yes (Y)'	Ayssa Valente (b) (4) (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	05 Apr 2021 12:31:09
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	05 Apr 2021 12:30:55
Signature has been broken.	Erin Harrelson (b) (4)	05 Apr 2021 12:30:55
User entered '03 Mar 2021' reason for change: Data Entry Error	(b) (4)	05 Apr 2021 12:30:55
User signature succeeded.	Erin Harrelson (b) (4)	05 Apr 2021 12:30:55
User entered empty.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
	Ayssa Valente (b) (4)	02 Mar 2021 17:06:21
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'No (N)'	Ayssa Valente (b) (4)	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User entered empty.	System	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User entered empty.	System	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:12
User entered empty.	System	02 Mar 2021 17:06:21

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 11:08:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 11:08:56
Data point term sent to Coder	System	02 Mar 2021 17:07:16
User entered 'ketorolac'	Ayssa Valente (b) (4) (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'No (N)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'kidney stone'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '10'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'mg (mg)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:58
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'as needed (PRN)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Oral (ORAL)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '27 Feb 2021'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '0'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:14
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	05 Apr 2021 12:40:18
Signature has been broken.	Erin Harrelson (b) (4) (b) (4)	05 Apr 2021 12:39:34
User entered 'No (N)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	05 Apr 2021 12:39:34
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:33:08
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered 'Yes (Y)'	Ayssa Valente (b) (4) (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
Signature has been broken.	Erin Harrelson (b) (4)	05 Apr 2021 12:39:34
User entered '03 Mar 2021' reason for change: Data Entry Error	Erin Harrelson (b) (4)	05 Apr 2021 12:39:34
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	Ayssa Valente (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'No (N)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User entered empty.	System	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User entered empty.	System	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:19
User entered empty.	System	02 Mar 2021 17:06:58

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 17:08:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 17:08:43
Data point term sent to Coder	System	02 Mar 2021 17:08:16
User entered 'tamsulosin'	Ayssa Valente (b) (4) (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'No (N)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'kidney stone'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '0.4'	Ayssa Valente (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'mg (mg)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:07:47
	(b) (4)	

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'once daily (QD)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'Oral (ORAL)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '27 Feb 2021'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered '0'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:41:22
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	05 Apr 2021 12:41:22
Signature has been broken.	Erin Harrelson (b) (4) (b) (4)	05 Apr 2021 12:40:47
User entered 'No (N)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	05 Apr 2021 12:40:47
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:34:09
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:12:25
User entered 'Yes (Y)'	Ayssa Valente (b) (4) (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
Signature has been broken.	Erin Harrelson (b) (4)	05 Apr 2021 12:40:47
User entered '03 Mar 2021' reason for change: Data Entry Error	Erin Harrelson (b) (4)	05 Apr 2021 12:40:47
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered empty.	Ayssa Valente (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
User entered 'No (N)'	(b) (4) Ayssa Valente (b) (4)	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User entered '1'	System	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User entered '1'	System	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:40:22
User entered '804 (804)'	System	02 Mar 2021 17:07:47

US3082122

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:05:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Megan Marles (b) (4)	05 Apr 2021 17:46:23
	(b) (4)	
Signature has been broken.	Megan Marles (b) (4)	05 Apr 2021 17:45:30
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Marles (b) (4)	05 Apr 2021 17:45:30
	(b) (4)	
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:12:25
	(b) (4)	
User entered 'No (N)'	Ayssa Valente (b) (4)	03 Mar 2021 14:29:50
	(b) (4)	

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:45
User entered 'USA-US114-2021-MRNA-1273-P301000007'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Yes (Y)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Yes (Y)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Barton'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Williams'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered '3806 Peachtree Ave.'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Wilmington'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'NC'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered '28403'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'US'	System	29 Mar 2021 15:04:43

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Apr 2021 14:23:18
User entered '1'	System	29 Mar 2021 15:04:43

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:45
User entered 'USA-US114-2021-MRNA-1273-P301000007'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Yes (Y)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Yes (Y)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Barton'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Williams'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered '3806 Peachtree Ave.'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Wilmington'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'NC'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered '28403'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'US'	System	29 Mar 2021 15:04:43

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Apr 2021 14:23:18
User entered '1'	System	29 Mar 2021 15:04:43

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:05:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
User entered '29/Mar/2021 11:04'	System	29 Mar 2021 15:04:43

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:05:19

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.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 15:04:43

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:45
User entered 'USA-US114-2021-MRNA-1273-P301000007'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Yes (Y)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Yes (Y)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'No (N)'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Barton'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Williams'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered '3806 Peachtree Ave.'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'Wilmington'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'NC'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered '28403'	System	29 Mar 2021 15:04:11

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:04:49
User entered 'US'	System	29 Mar 2021 15:04:43

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Apr 2021 14:23:18
User entered '1'	System	29 Mar 2021 15:04:43

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:05:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 03:43:05
User entered '06/Apr/2021 10:23'	System	06 Apr 2021 14:23:18

US3082122

Folder: SAE USA-US114-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:05:19

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.	Barton Williams (b) (4)	16 Apr 2021 12:25:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 03:43:05
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 14:23:18