

US3202042 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:41:24

All time stamps listed in this document are displayed in GMT

US3202042

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

[Participant ID](#)

US3202042

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

US3202042

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	49
Age Units	YEARS
Age (Derived)	49
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

US3202042

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Date of Informed Consent (<i>dd MMM yyyy</i>)	6 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3202042

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Were any significant conditions reported?

Yes ☒

No ☐

US3202042

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Condition	KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

US3202042

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Condition	ALLERGY TO NSAIDS
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3202042

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Condition	
Start date (dd MMM yyyy)	
Start date completely unknown	
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3202042

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:39 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 15:39
Height (<i>xxx.x</i>)	164.9 cm
Weight (<i>xxx.x</i>)	58.3 kg
BMI (<i>xxx.x</i>)	21.44012 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 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) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

Date of assessment (dd MMM yyyy) 6 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2011

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

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) 13 Feb 2021 01:50:16

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	True
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) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

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

What was the participant's randomization number? 101726

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

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) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

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)	06 AUG 2020
Time of assessment (00:00-23:59)	15:39 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 15:39
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	16:59 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:59
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	66 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)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

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) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 6 AUG 2020

What was the treatment time? (00:00-23:59) 16:13 (24 HR)

Treatment Date and Time (derived) 6 AUG 2020 16:13

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) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 AUG 2020

Collection time (00:00-23:59)

15:52 (24 HR)

Collection date and time (derived)

06 AUG 2020 15:52

US3202042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Collection date (dd MMM yyyy)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:50	06 AUG 2020 15:50
Nasopharyngeal Swab 2	No		

US3202042

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 16:35

PC Open Date & Time

06 AUG 2020 16:33

PC Close Date & Time

06 AUG 2020 19:03

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

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

06 AUG 2020 19:58

PC Close Date & Time

07 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

07 AUG 2020 19:04

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 20:49

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 19:18

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 18:57

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 20:53

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

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

98.0 °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

12 AUG 2020 19:59

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 16:39

PC Open Date & Time

06 AUG 2020 16:33

PC Close Date & Time

06 AUG 2020 19:03

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 06:30

PC Open Date & Time

06 AUG 2020 19:58

PC Close Date & Time

07 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

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 ☐

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

25

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

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

Yes ☒

No ☐

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

25

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 19:06

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 20:49

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 19:15

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 18:57

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 20:53

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 19:59

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 16:40
PC Open Date & Time	06 AUG 2020 16:33
PC Close Date & Time	06 AUG 2020 19:03

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

06 AUG 2020 19:58

PC Close Date & Time

07 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

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 ☒

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 19:06
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

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

50 of 2221

EAB) (1725)

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 20:50
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2221

EAB) (1725)

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 19:16
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

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 ☒

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 18:58
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2221

EAB) (1725)

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 20:54
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

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 ☒

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202042

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202042

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

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)	10 SEP 2020
Time of assessment (00:00-23:59)	15:03 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 15:03
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

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)	10 SEP 2020
Time of assessment (00:00-23:59)	16:25 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 16:25
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3202042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

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.

US3202042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 15:42 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 15:42

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

US3202042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	15:12 (24 HR)
Collection date and time (derived)	10 SEP 2020 15:12

US3202042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:11	10 SEP 2020 15:11
Nasopharyngeal Swab 2	No		

US3202042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 16:20

PC Open Date & Time

10 SEP 2020 16:02

PC Close Date & Time

10 SEP 2020 18:32

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	10 SEP 2020 20:55
PC Open Date & Time	10 SEP 2020 19:27
PC Close Date & Time	11 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

100.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 20:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 21:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

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

98.2 °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

13 SEP 2020 18:59

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

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

14 SEP 2020 17:41

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 13:17

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 04:33

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

10 SEP 2020 16:14

PC Open Date & Time

10 SEP 2020 16:02

PC Close Date & Time

10 SEP 2020 18:32

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

10 SEP 2020 20:56

PC Open Date & Time

10 SEP 2020 19:27

PC Close Date & Time

11 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

11 SEP 2020 20:01

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

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

12 SEP 2020 21:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

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

13 SEP 2020 19:00

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

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

14 SEP 2020 17:42

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

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

15 SEP 2020 13:17

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

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

17 SEP 2020 04:33

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 16:15
PC Open Date & Time	10 SEP 2020 16:02
PC Close Date & Time	10 SEP 2020 18:32

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 20:56
PC Open Date & Time	10 SEP 2020 19:27
PC Close Date & Time	11 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

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 ☒

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 20:02
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

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 ☒

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 21:53
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

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 ☒

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:00
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2221

EAB) (1725)

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 17:43
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

102 of 2221

EAB) (1725)

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 13:18
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

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 ☒

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 04:34
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3202042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202042

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202042

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:49:31

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:33 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 14:33
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

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.

US3202042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 OCT 2020

Collection time (00:00-23:59)

14:40 (24 HR)

Collection date and time (derived)

08 OCT 2020 14:40

US3202042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:50:16

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 OCT 2020 10:53:20

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 OCT 2020 12:08:00

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 04:27:08

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 14:42:23
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 09:45:35
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 03:52:13

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 12:25:16

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

28 NOV 2020 07:20:16

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

05 DEC 2020 11:18:36

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 12:50:17
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 <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	19 DEC 2020 13:04:59
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 10:30:25

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 07:06:50
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	09 JAN 2021 04:56:08
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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	16 JAN 2021 09:30:21
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	23 JAN 2021 08:34:46
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 15:17:39

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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	13 FEB 2021 07:51:42
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 13:24:40

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 06:22:23

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 06:14:08

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	14 MAR 2021 07:52:27
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 07:20:15

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 18:18:28

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

14 APR 2021 07:28:28

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 08:21:11

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 06:23:50

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 20:41:38

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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°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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 MAY 2021 00:01
Patient Cloud Close Date & Time	26 MAY 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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°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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	09 FEB 2022 23:59
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US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	30 MAR 2022 23:59
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US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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="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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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°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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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"/>

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐
Yes ☐

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:41:24

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		06 MAR 2021 06:14:30

US3202042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:37:24

Generated On: 09 Jun 2021 15:41:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202042

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:37:24

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:18:10

Generated On: 09 Jun 2021 15:41:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202042

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:18:10

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:18:10

Generated On: 09 Jun 2021 15:41:24

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments X 3 ATTEMPTS; LEFT VM

If Contact Not Made, please provide Comments

US3202042

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:18:10

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:18:10

Generated On: 09 Jun 2021 15:41:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202042

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:18:10

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:18:10

Generated On: 09 Jun 2021 15:41:24

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

Visit date (dd MMM yyyy)	3 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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US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:18:10

Generated On: 09 Jun 2021 15:41:24

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) _____

US3202042

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:18:10

Generated On: 09 Jun 2021 15:41:24

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.

US3202042

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:18:10

Generated On: 09 Jun 2021 15:41:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 MAR 2021
Collection time (00:00-23:59)	08:33 (24 HR)
Collection date and time (derived)	3 MAR 2021 08:33

US3202042

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:18:10

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202042

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3202042

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:24

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"/>

US3202042

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:41:24

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3202042

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

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

Visit date (dd MMM yyyy)	04 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3202042

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 17:52:53

Generated On: 09 Jun 2021 15:41:24

Date of updated informed consent (dd MMM yyyy) 04 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 04 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3202042

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 JAN 2021
Collection time (00:00-23:59)	15:18 (24 HR)
Collection date and time (derived)	04 JAN 2021 15:18

US3202042

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 JAN 2021
Collection time (00:00 - 23:59)	15:15
Collection Date and Time (derived)	04 JAN 2021 15:15

US3202042

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 13:01:55

Generated On: 09 Jun 2021 15:41:24

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

AEID	USA-US128-2021-MRNA-1273-P30 1000005
Adverse event	DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR - PARTIALLY OCCLUSIVE
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)	06 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	07 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	11 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

	Unknown	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
<hr/>		
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"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

UPDATE 29/JAN/2021--MEDICAL
RECORDS RECEIVED
YESTERDAY AFTERNOON AND
REVIEWED BY SUB-I AND SC,
RESULTING IN UPDATED
INFORMATION REGARDING AE
TERM, HOSPITALIZATION
DATES, ETC. SUBJECT HAD
OUTPATIENT COSMETIC
SURGERY (BILATERAL
BRACHIOPLASTY AND
BILATERAL THIGH LIFT) ON
05JAN2021. SHE REPORTED TO
ER ON 07/JAN/2021 FOR
SWELLING AND PAIN. SHE WAS
FOUND TO HAVE DVTS,
HOSPITALIZED THROUGH
11/JAN/2021 D/C ON XARELTO..
SITE NOTIFIED ON 11/JAN/21
THAT SUBJECT HAD COSMETIC
SURGERY ON ARMS ON
05JAN21 AND DEVELOPED A
BLOOD CLOT IN HER NECK SO
SHE WAS KEPT AT HOSPITAL.
DETAILS PROVIDED BY FRIEND
VIA PHONE. RECORDS
REQUESTED AND WILL
UPDATE WHEN MORE
INFORMATION COLLECTED.

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

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

AEID

Adverse event

RIGHT GROIN HEMATOMA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

AEID	
Adverse event	RIGHT LEG PAINFUL SWELLING
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)	19 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

AEID	USA-US128-2021-MRNA-1273-P30 1000005
Adverse event	DVT- OCCLUSIVE LEFT SUBCLAVIAN VEIN
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)	6 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	7 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	11 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 13:18:09

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

AEID	
Adverse event	PHLEBITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

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

Yes ☒

No ☐

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

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 150

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) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Name of Medication TOPAMAX

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

	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 2019	
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)	3	
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) 09 Apr 2021 13:18:09

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Name of Medication HEPARIN (PORCINE 5,000 UNITS/ML)

Prophylaxis Yes ☐
No ☒

Indication DEEP VEIN THROMBOSIS LEFT
INTERNAL JUGULAR AND
SUBCLAVIAN VEINS

Dose per administration 5000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 13:18:09

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	08 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Name of Medication XARELTO (DOSAGE CHANGED)

Prophylaxis Yes ☐
No ☒

Indication DEEP VEIN THROMBOSIS LEFT
INTERNAL JUGULAR AND
SUBCLAVIAN VEINS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	07 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication DEEP VEIN THROMBOSIS LEFT
INTERNAL JUGULAR AND
SUBCLAVIAN VEINS

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

VARIABLE DRIP

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) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	07 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 JAN 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 (6)

Data signed: (b) (4) 09 Apr 2021 13:18:09

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Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication RIGHT LEG HEMATOMA

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 (6)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

	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)		12 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 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 (7)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication RIGHT LEG HEMATOMA

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 (7)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

	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)		12 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 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 (8)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Name of Medication NORMAL SALINE FLUIDS

Prophylaxis Yes ☐
No ☒

Indication RIGHT GROIN HEMATOMA

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 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 (9)

Data signed: (b) (4) 09 Apr 2021 13:18:09

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Name of Medication GENERAL ANESTHESIA

Prophylaxis Yes ☐
No ☒

Indication RIGHT GROIN HEMATOMA

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

	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)		12 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 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) 09 Apr 2021 13:18:09

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Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication RIGHT LEG PAINFUL SWELLING

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 (10)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

	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)		19 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 JAN 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) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication RIGHT LEG PAINFUL SWELLING

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 (11)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication PAINFUL LEG SWELLING

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 (12)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	19 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Name of Medication XARELTO

Prophylaxis Yes ☐
No ☒

Indication PHLEBITIS IN BOTH LEGS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

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

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 JAN 2021	INCISION AND DRAINAGE OF RIGHT GROIN HEMATOMA	Adverse Event	
05 JAN 2021	BILATERAL BRACHIOPLASTY	Other	COSMETIC
05 JAN 2021	BILATERAL THIGH LIFT	Other	COSMETIC

US3202042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:41:24

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 ☐

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

SAEID	USA-US128-2021-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

SAEID	USA-US128-2021-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/JAN/2021 18:57
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

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

SAEID	USA-US128-2021-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	25/JAN/2021 19:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

SAEID	USA-US128-2021-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	29/JAN/2021 13:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

SAEID	USA-US128-2021-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	01/FEB/2021 13:22
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

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

SAEID	USA-US128-2021-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	11/FEB/2021 12:06
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

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

SAEID	USA-US128-2021-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	11/FEB/2021 12:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

SAEID	USA-US128-2021-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	11/FEB/2021 14:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Data signed: (b) (4) 09 Apr 2021 13:18:09

Generated On: 09 Jun 2021 15:41:24

SAEID	USA-US128-2021-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	11/FEB/2021 14:55
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

US3202042 (Prod: WR-ClinSearch, LLC)

US3202042

Form: Participant Creation

Generated On: 09 Jun 2021 15:41:24

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:31:38
User entered 'US3202042'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:30:01

US3202042

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:35:14
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 19:49:05

US3202042

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:35:14
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:30:02

US3202042

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:35:14
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 19:49:05

US3202042

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered 'SCRN'	System	06 Aug 2020 19:49:05

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:30:03

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered '49'	(b) (4), (b) (6)	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered 'YEARS'	System	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered '49'	System	06 Aug 2020 19:49:24

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered 'Female (F)'	(b) (4), (b) (6)	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered 'l'	(b) (4), (b) (6)	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:24

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:36:25
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:11:43

US3202042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:24

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:17:26
User entered '6 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 19:49:24

US3202042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered 'Aug 2020'	System	06 Aug 2020 19:49:24

US3202042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered '2020'	System	06 Aug 2020 19:49:24

US3202042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:24

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:17:26
User entered 'Amendment 1 (1)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 19:49:24

US3202042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:17:26
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 19:49:24

US3202042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:17:26
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 19:49:24

US3202042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:17:26
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 19:49:24

US3202042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:24

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:17:26
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 19:49:24

US3202042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:17:26
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:30:02

US3202042

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered 'I'	System	06 Aug 2020 19:49:30

US3202042

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:37:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 19:49:30

US3202042

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:41:24

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
User closed query 'PE= Lateral Nystagmus and per eDC guidelines any abnormal PE finding must be captured as MH or AE, Please verify. Also need to include condition treated by medication for "sleep".' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 14:42:38
Query 'PE= Lateral Nystagmus and per eDC guidelines any abnormal PE finding must be captured as MH or AE, Please verify. Also need to include condition treated by medication for "sleep".' answered with 'Updated' (Site from CRA).	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:21:23
User opened query 'PE= Lateral Nystagmus and per eDC guidelines any abnormal PE finding must be captured as MH or AE, Please verify. Also need to include condition treated by medication for "sleep".' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 15:52:11
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 15:39:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:11:55

US3202042

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:13:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:13:15
Data point term sent to Coder	System	11 Aug 2020 18:12:44
User entered 'Kidney Stones'	(b) (4), (b) (6)	11 Aug 2020 18:12:28

US3202042

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered 'UN UNK 2011'	(b) (4), (b) (6)	11 Aug 2020 18:12:28

US3202042

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:12:28

US3202042

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:12:28

US3202042

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered 'UN UNK 2011'	(b) (4), (b) (6)	11 Aug 2020 18:12:28

US3202042

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:12:28

US3202042

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered 'Jan 2011'	System	11 Aug 2020 18:12:28

US3202042

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered '2011'	System	11 Aug 2020 18:12:28

US3202042

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered 'Jan 2011'	System	11 Aug 2020 18:12:28

US3202042

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered '2011'	System	11 Aug 2020 18:12:28

US3202042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:15:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:15:17
Data point term sent to Coder	System	11 Aug 2020 18:13:45
User entered 'Hysterectomy'	(b) (4), (b) (6)	11 Aug 2020 18:13:00

US3202042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered 'UN UNK 2011'	(b) (4), (b) (6)	11 Aug 2020 18:13:00

US3202042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:13:00

US3202042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:13:00

US3202042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered 'UN UNK 2011'	(b) (4), (b) (6)	11 Aug 2020 18:13:00

US3202042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:13:00

US3202042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered 'Jan 2011'	System	11 Aug 2020 18:13:00

US3202042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered '2011'	System	11 Aug 2020 18:13:00

US3202042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered 'Jan 2011'	System	11 Aug 2020 18:13:00

US3202042

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered '2011'	System	11 Aug 2020 18:13:00

US3202042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:15:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:15:18
Data point term sent to Coder	System	11 Aug 2020 18:13:47
User entered 'Back Pain'	(b) (4), (b) (6)	11 Aug 2020 18:13:38

US3202042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered 'UN UNK 2006'	(b) (4), (b) (6)	11 Aug 2020 18:13:38

US3202042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:13:38

US3202042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:13:38

US3202042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:13:38

US3202042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:13:38

US3202042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered 'Jan 2006'	System	11 Aug 2020 18:13:38

US3202042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered '2006'	System	11 Aug 2020 18:13:38

US3202042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered empty.	System	11 Aug 2020 18:13:38

US3202042

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered empty.	System	11 Aug 2020 18:13:38

US3202042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:15:19
Data point term sent to Coder	System	11 Aug 2020 18:14:49
User entered 'Allergy to NSAIDs'	(b) (4), (b) (6)	11 Aug 2020 18:13:54

US3202042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:13:54

US3202042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 18:13:54

US3202042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:13:54

US3202042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:13:54

US3202042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:40:20
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:13:54

US3202042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered empty.	System	11 Aug 2020 18:13:54

US3202042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered empty.	System	11 Aug 2020 18:13:54

US3202042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered empty.	System	11 Aug 2020 18:13:54

US3202042

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered empty.	System	11 Aug 2020 18:13:54

US3202042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:14:02
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 16:18:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 16:18:40
Data point term sent to Coder	System	22 Sep 2020 16:17:23
User entered 'Insomnia'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:16:30

US3202042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:14:07
User entered 'un UNK 2017'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:16:30

US3202042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:14:14
User entered '0'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:16:30

US3202042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:14:12
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:16:30

US3202042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:14:16
User entered empty.	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:16:30

US3202042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:14:18
User entered '0'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:16:30

US3202042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered 'Jan 2017'	System	22 Sep 2020 16:16:30

US3202042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered '2017'	System	22 Sep 2020 16:16:30

US3202042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:24

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

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

US3202042

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:24

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

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

US3202042

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16

US3202042

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16

US3202042

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16

US3202042

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16

US3202042

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16

US3202042

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16

US3202042

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16

US3202042

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16

US3202042

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16

US3202042

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:47:29
User entered '6 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:47:29
User entered '15:39'	(b) (4), (b) (6)	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered '6 Aug 2020 15:39'	System	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:47:29
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 17:38:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Aug 2020 17:38:03
User entered '164.9' cm reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 17:38:03
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:16:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:16:14
DataPoint set to visible.	System	06 Aug 2020 19:49:30

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:47:29
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 17:38:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Aug 2020 17:38:03
User entered '58.3' kg reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 17:38:03
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:16:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:16:14
DataPoint set to visible.	System	06 Aug 2020 19:49:30

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
Amendment Manager: User entered '21.44012'	System	16 Sep 2020 23:46:13
User entered '21.4'	System	15 Aug 2020 17:38:03
User entered empty.	System	11 Aug 2020 18:16:14
DataPoint set to visible.	System	06 Aug 2020 19:49:30

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User entered 'kg/m2'	System	15 Aug 2020 17:38:03
User entered empty.	System	11 Aug 2020 18:16:14
DataPoint set to visible.	System	06 Aug 2020 19:49:30

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:47:29
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 17:38:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Aug 2020 17:38:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 17:38:03
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:16:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:04:35
User closed query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 12:14:08
Query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	15 Dec 2020 18:39:43
DataPoint Un-verified.	zackery harmon (b) (4) (b) (4)	15 Dec 2020 18:39:37
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4) (b) (4)	15 Dec 2020 18:39:37
User opened query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 15:43:34
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 15:47:29
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 17:38:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).		15 Aug 2020 17:38:03
User entered 'Other (Other)' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 17:38:03
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:16:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:47:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4)	15 Aug 2020 17:38:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
User closed query 'Per CDM: Pulse, Respiratory Rate, Systolic/Diastolic Blood Pressure is recorded as Not Done. Kindly remove beats/min, breaths/min, or mmHg.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 08:29:32
Query 'Per CDM: Pulse, Respiratory Rate, Systolic/Diastolic Blood Pressure is recorded as Not Done. Kindly remove beats/min, breaths/min, or mmHg.' answered with 'ERRONEOUS QUERY--THE UNITS ARE NOT ENTERED BY SITE STAFF AND CANNOT BE REMOVED BY SITE STAFF EITHER' (Site from DM).	Erica Osmundsen (b) (4)	15 Jan 2021 20:25:40
User opened query 'Per CDM: Pulse, Respiratory Rate, Systolic/Diastolic Blood Pressure is recorded as Not Done. Kindly remove beats/min, breaths/min, or mmHg.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 14:21:47
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 15:47:29
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 17:38:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Aug 2020 17:38:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 17:38:03
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:16:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
Query 'Per CDM: Please remove data from this field, this should be blank if Pulse is Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 08:29:16
User opened query 'Per CDM: Please remove data from this field, this should be blank if Pulse is Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 14:21:59
User entered 'bpm'	System	15 Aug 2020 17:38:03
User entered empty.	System	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:47:29
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 17:38:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Aug 2020 17:38:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 17:38:03
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:16:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
Query 'Per CDM: Please remove data from this field, this should be blank if Respiratory Rate is Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 08:29:14
User opened query 'Per CDM: Please remove data from this field, this should be blank if Respiratory Rate is Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 14:22:27
User entered 'breaths/min'	System	15 Aug 2020 17:38:03
User entered empty.	System	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:47:29
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 17:38:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Aug 2020 17:38:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 17:38:03
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:16:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
Query 'Per CDM: Please remove data from this field, this should be blank if Systolic Blood Pressure is Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 08:29:19
User opened query 'Per CDM: Please remove data from this field, this should be blank if Systolic Blood Pressure is Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 14:22:51
User entered 'mmHg'	System	15 Aug 2020 17:38:03
User entered empty.	System	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:47:29
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 17:38:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Aug 2020 17:38:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 17:38:03
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:16:14
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
Query 'Per CDM: Please remove data from this field, this should be blank if Diastolic Blood Pressure is Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 08:29:21
User opened query 'Per CDM: Please remove data from this field, this should be blank if Diastolic Blood Pressure is Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 14:23:19
User entered 'mmHg'	System	15 Aug 2020 17:38:03
User entered empty.	System	11 Aug 2020 18:16:14

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16

US3202042

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16

US3202042

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:47:55
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	29 Aug 2020 16:44:48
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	15 Aug 2020 17:39:12
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	15 Aug 2020 17:38:56
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 17:38:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:16:26

US3202042

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:47:55
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 15:05:23
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		10 Sep 2020 20:02:26
User entered '06 Aug 2020' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	29 Aug 2020 16:44:48
User entered empty; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 17:39:12
User entered '6 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:16:26

US3202042

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:48:18
User entered '6 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:16:50

US3202042

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:48:18
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:16:50

US3202042

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:48:18
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	11 Aug 2020 18:16:50

US3202042

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:24

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:48:18
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:16:50

US3202042

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:48:18
User entered 'UN UNK 2011'	(b) (4), (b) (6)	11 Aug 2020 18:16:50

US3202042

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:24

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:48:18
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:16:50

US3202042

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:48:18
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:16:50

US3202042

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:41:24

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:48:18
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:16:50

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

[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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

[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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

[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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

[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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

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 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered 'l'	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:38:16
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:49:12
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:17:45

US3202042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:54:50
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 19:49:44

US3202042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
User closed query 'please complete entry for lab collection(15:52) and NP swab collected (15:50) per source, please verify' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:20:47
Query 'please complete entry for lab collection(15:52) and NP swab collected (15:50) per source, please verify' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 20:56:36
User opened query 'please complete entry for lab collection(15:52) and NP swab collected (15:50) per source, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 16:06:28
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 15:54:50
User entered '6 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 19:49:44

US3202042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:54:50
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 19:49:44

US3202042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'VISIT1'	System	06 Aug 2020 19:49:44

US3202042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:54:59
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:39:40

US3202042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:24

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:54:59
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:39:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:39:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 19:39:40
User entered '101726' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:39:40

US3202042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:24

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:54:59
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:39:40

US3202042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:24

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)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:54:59
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:18:38

US3202042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:24

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)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:54:59
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:18:38

US3202042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:24

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:54:59
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:18:38

US3202042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:24

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:54:59
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:18:38

US3202042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:24

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:54:59
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:18:38

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User closed query 'Per CDM: Per CCGs pages 15-16, height should be marked as "ND." Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 13:23:22
Query 'Per CDM: Per CCGs pages 15-16, height should be marked as "ND." Please update accordingly ' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:59:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:59:20
User opened query 'Per CDM: Per CCGs pages 15-16, height should be marked as "ND." Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 18:57:17
User entered '164.9' cm	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User closed query 'Per CDM: Per CCGs pages 15-16, weight should be marked as "ND." Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 13:23:23
Query 'Per CDM: Per CCGs pages 15-16, weight should be marked as "ND." Please update accordingly ' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:59:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:59:20
User opened query 'Per CDM: Per CCGs pages 15-16, weight should be marked as "ND." Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 18:57:26
User entered '58.3' kg	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User closed query 'Per CDM: Per CCGs pages 15-16, height should be marked as "ND." Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 13:23:22
Query 'Per CDM: Per CCGs pages 15-16, height should be marked as "ND." Please update accordingly ' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:59:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:59:20
User opened query 'Per CDM: Per CCGs pages 15-16, height should be marked as "ND." Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 18:57:17
User entered '164.9' cm	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User closed query 'Per CDM: Per CCGs pages 15-16, weight should be marked as "ND." Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 13:23:23
Query 'Per CDM: Per CCGs pages 15-16, weight should be marked as "ND." Please update accordingly ' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:59:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:59:20
User opened query 'Per CDM: Per CCGs pages 15-16, weight should be marked as "ND." Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 18:57:26
User entered '58.3' kg	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '06 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '15:39'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '06 Aug 2020 15:39'	System	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '37.1' C	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '66'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'bpm'	System	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '16'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'breaths/min'	System	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '110'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'mmHg'	System	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '60'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'mmHg'	System	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User closed query 'Per CDM: Per CCGs pages 15-16, height should be marked as "ND." Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 13:23:22
Query 'Per CDM: Per CCGs pages 15-16, height should be marked as "ND." Please update accordingly ' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:59:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:59:20
User opened query 'Per CDM: Per CCGs pages 15-16, height should be marked as "ND." Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 18:57:17
User entered '164.9' cm	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User closed query 'Per CDM: Per CCGs pages 15-16, weight should be marked as "ND." Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 13:23:23
Query 'Per CDM: Per CCGs pages 15-16, weight should be marked as "ND." Please update accordingly ' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:59:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:59:20
User opened query 'Per CDM: Per CCGs pages 15-16, weight should be marked as "ND." Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 18:57:26
User entered '58.3' kg	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '06 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 17:26:49
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 18:21:07
User entered '16:59'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '06 Aug 2020 16:59'	System	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '37.1' C	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '66'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'bpm'	System	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '16'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'breaths/min'	System	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '124'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'mmHg'	System	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:56:17
User entered '82'	(b) (4), (b) (6)	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'mmHg'	System	11 Aug 2020 18:21:07

US3202042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:00:59
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4)	29 Aug 2020 16:44:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:21:49

US3202042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:00:59
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	29 Aug 2020 16:44:29
User entered '6 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:21:49

US3202042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:03:46
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 20:23:30

US3202042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:03:46
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 20:23:30

US3202042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

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)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:03:46
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 20:23:30

US3202042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 20:23:30

US3202042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:03:46
User entered '6 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 20:23:30

US3202042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:03:46
User entered '16:13'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 20:23:30

US3202042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '6 Aug 2020 16:13'	System	06 Aug 2020 20:23:30

US3202042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:03:46
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 20:23:30

US3202042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:03:46
User entered 'ONCE'	System	06 Aug 2020 20:23:30

US3202042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 20:23:30

US3202042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:21:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:56:22

US3202042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:21:16
User entered '06 Aug 2020'	(b) (4), (b) (6)	16 Sep 2020 20:56:22

US3202042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:21:16
User entered '15:52'	(b) (4), (b) (6)	16 Sep 2020 20:56:22

US3202042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '06 Aug 2020 15:52'	System	16 Sep 2020 20:56:22

US3202042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:41:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:21:24
User entered '06 Aug 2020'	(b) (4), (b) (6)	16 Sep 2020 20:56:55

US3202042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Sep 2020 20:56:55

US3202042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:21:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:56:55

US3202042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:24

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:21:24
User entered '15:50'	(b) (4), (b) (6)	16 Sep 2020 20:56:55

US3202042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '06 Aug 2020 15:50'	System	16 Sep 2020 20:56:55

US3202042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Sep 2020 20:56:55

US3202042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:21:24
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 20:56:55

US3202042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:21:24
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:56:55

US3202042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered empty.	System	16 Sep 2020 20:56:55

US3202042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:08:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:22:05

US3202042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '1'	System	11 Aug 2020 18:22:05

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:34:21', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0f5f0de1-3411-4a72-99cd-3c542f92f490'	System	06 Aug 2020 20:35:06
User entered 'Yes (Y)'	System	06 Aug 2020 20:35:06

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:34:42', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0f5f0de1-3411-4a72-99cd-3c542f92f490'	System	06 Aug 2020 20:35:06
User entered '98.7'	System	06 Aug 2020 20:35:06

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:34:49', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0f5f0de1-3411-4a72-99cd-3c542f92f490'	System	06 Aug 2020 20:35:06
User entered 'No (N)'	System	06 Aug 2020 20:35:06

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:35:03', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0f5f0de1-3411-4a72-99cd-3c542f92f490'	System	06 Aug 2020 20:35:06
User entered '06 Aug 2020 16:35'	System	06 Aug 2020 20:35:06

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '06 Aug 2020 16:33'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '06 Aug 2020 19:03'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '06 Aug 2020 19:58'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 2'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:04:18', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bd96a9f3-f801-4cfc-bd22-acca34675a2e'	System	07 Aug 2020 23:04:42
User entered 'Yes (Y)'	System	07 Aug 2020 23:04:42

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:04:26', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bd96a9f3-f801-4cfc-bd22-acca34675a2e'	System	07 Aug 2020 23:04:42
User entered '97.7'	System	07 Aug 2020 23:04:42

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:04:32', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bd96a9f3-f801-4cfc-bd22-acca34675a2e'	System	07 Aug 2020 23:04:42
User entered 'No (N)'	System	07 Aug 2020 23:04:42

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:04:37', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bd96a9f3-f801-4cfc-bd22-acca34675a2e'	System	07 Aug 2020 23:04:42
User entered '07 Aug 2020 19:04'	System	07 Aug 2020 23:04:42

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 3'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:49:10', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '453f2c01-50c2-4e62-af40-2cdd1039c7fd'	System	09 Aug 2020 00:49:35
User entered 'Yes (Y)'	System	09 Aug 2020 00:49:35

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:49:23', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '453f2c01-50c2-4e62-af40-2cdd1039c7fd'	System	09 Aug 2020 00:49:35
User entered '97.5'	System	09 Aug 2020 00:49:35

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:49:27', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '453f2c01-50c2-4e62-af40-2cdd1039c7fd'	System	09 Aug 2020 00:49:35
User entered 'No (N)'	System	09 Aug 2020 00:49:35

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:49:33', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '453f2c01-50c2-4e62-af40-2cdd1039c7fd'	System	09 Aug 2020 00:49:35
User entered '08 Aug 2020 20:49'	System	09 Aug 2020 00:49:35

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 4'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:17:54', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd9b9cba6-a98c-4d9b-92eb-8e13b49f23c1'	System	09 Aug 2020 23:18:13
User entered 'Yes (Y)'	System	09 Aug 2020 23:18:13

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:18:01', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd9b9cba6-a98c-4d9b-92eb-8e13b49f23c1'	System	09 Aug 2020 23:18:13
User entered '98.4'	System	09 Aug 2020 23:18:13

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:18:04', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd9b9cba6-a98c-4d9b-92eb-8e13b49f23c1'	System	09 Aug 2020 23:18:13
User entered 'No (N)'	System	09 Aug 2020 23:18:13

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:18:10', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd9b9cba6-a98c-4d9b-92eb-8e13b49f23c1'	System	09 Aug 2020 23:18:13
User entered '09 Aug 2020 19:18'	System	09 Aug 2020 23:18:13

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 5'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:57:06', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '207b4a28-6055-4f16-9a85-d56452c122d2'	System	10 Aug 2020 22:57:26
User entered 'Yes (Y)'	System	10 Aug 2020 22:57:26

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:57:13', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '207b4a28-6055-4f16-9a85-d56452c122d2'	System	10 Aug 2020 22:57:26
User entered '97.9'	System	10 Aug 2020 22:57:26

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:57:17', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '207b4a28-6055-4f16-9a85-d56452c122d2'	System	10 Aug 2020 22:57:26
User entered 'No (N)'	System	10 Aug 2020 22:57:26

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:57:22', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '207b4a28-6055-4f16-9a85-d56452c122d2'	System	10 Aug 2020 22:57:26
User entered '10 Aug 2020 18:57'	System	10 Aug 2020 22:57:26

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 6'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:53:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '821dd98b-0b49-4b4e-9181-d6cda918883f'	System	12 Aug 2020 00:53:23
User entered 'Yes (Y)'	System	12 Aug 2020 00:53:23

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:53:07', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '821dd98b-0b49-4b4e-9181-d6cda918883f' User entered '98.1'	System	12 Aug 2020 00:53:23
	System	12 Aug 2020 00:53:23

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:53:10', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '821dd98b-0b49-4b4e-9181-d6cda918883f'	System	12 Aug 2020 00:53:23
User entered 'No (N)'	System	12 Aug 2020 00:53:23

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:53:20', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '821dd98b-0b49-4b4e-9181-d6cda918883f'	System	12 Aug 2020 00:53:23
User entered '11 Aug 2020 20:53'	System	12 Aug 2020 00:53:23

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 7'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:58:49', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd6219055-c675-476e-aab1-03edc78d6d15'	System	12 Aug 2020 23:59:08
User entered 'Yes (Y)'	System	12 Aug 2020 23:59:08

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:58:57', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd6219055-c675-476e-aab1-03edc78d6d15'	System	12 Aug 2020 23:59:08
User entered '98.0'	System	12 Aug 2020 23:59:08

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:59:01', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd6219055-c675-476e-aab1-03edc78d6d15'	System	12 Aug 2020 23:59:08
User entered 'No (N)'	System	12 Aug 2020 23:59:08

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:59:06', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd6219055-c675-476e-aab1-03edc78d6d15'	System	12 Aug 2020 23:59:08
User entered '12 Aug 2020 19:59'	System	12 Aug 2020 23:59:08

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:39:09', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '25fdff8a-22e0-44b4-be19-32feb328732c'	System	06 Aug 2020 20:39:45
User entered 'None (1)'	System	06 Aug 2020 20:39:45

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:39:15', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '25fdff8a-22e0-44b4-be19-32feb328732c'	System	06 Aug 2020 20:39:45
User entered 'No (N)'	System	06 Aug 2020 20:39:45

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:39:21', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '25fdff8a-22e0-44b4-be19-32feb328732c'	System	06 Aug 2020 20:39:45
User entered 'No (N)'	System	06 Aug 2020 20:39:45

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:39:33', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '25fdff8a-22e0-44b4-be19-32feb328732c'	System	06 Aug 2020 20:39:45
User entered 'None (1)'	System	06 Aug 2020 20:39:45

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:39:44', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '25fdff8a-22e0-44b4-be19-32feb328732c'	System	06 Aug 2020 20:39:45
User entered '06 Aug 2020 16:39'	System	06 Aug 2020 20:39:45

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '06 Aug 2020 16:33'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '06 Aug 2020 19:03'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T06:30:27', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'fb7c18e5-69f2-48c8-bafa-6fcba6b1152a'	System	07 Aug 2020 10:30:52
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 10:30:52

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T06:30:31', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'fb7c18e5-69f2-48c8-bafa-6fcba6b1152a'	System	07 Aug 2020 10:30:52
User entered 'No (N)'	System	07 Aug 2020 10:30:52

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T06:30:37', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'fb7c18e5-69f2-48c8-bafa-6fcba6b1152a'	System	07 Aug 2020 10:30:52
User entered 'No (N)'	System	07 Aug 2020 10:30:52

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T06:30:44', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'fb7c18e5-69f2-48c8-bafa-6fcba6b1152a'	System	07 Aug 2020 10:30:52
User entered 'None (1)'	System	07 Aug 2020 10:30:52

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T06:30:53', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'fb7c18e5-69f2-48c8-bafa-6fcba6b1152a'	System	07 Aug 2020 10:30:52
User entered '07 Aug 2020 06:30'	System	07 Aug 2020 10:30:52

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '06 Aug 2020 19:58'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 2'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:04:47', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8acbb45c-7fa0-4a86-a95e-fa34e5197fbb'	System	07 Aug 2020 23:06:16
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 23:06:16

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:04:52', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8acbb45c-7fa0-4a86-a95e-fa34e5197fbb'	System	07 Aug 2020 23:06:16
User entered 'Yes (Y)'	System	07 Aug 2020 23:06:16

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:05:32', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8acbb45c-7fa0-4a86-a95e-fa34e5197fbb' User entered '25'	System	07 Aug 2020 23:06:16
	System	07 Aug 2020 23:06:16

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:05:43', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8acbb45c-7fa0-4a86-a95e-fa34e5197fbb'	System	07 Aug 2020 23:06:16
User entered 'Yes (Y)'	System	07 Aug 2020 23:06:16

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:05:56', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8acbb45c-7fa0-4a86-a95e-fa34e5197fbb' User entered '25'	System	07 Aug 2020 23:06:16
	System	07 Aug 2020 23:06:16

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:06:02', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8acbb45c-7fa0-4a86-a95e-fa34e5197fbb'	System	07 Aug 2020 23:06:16
User entered 'None (1)'	System	07 Aug 2020 23:06:16

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:06:13', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8acbb45c-7fa0-4a86-a95e-fa34e5197fbb'	System	07 Aug 2020 23:06:16
User entered '07 Aug 2020 19:06'	System	07 Aug 2020 23:06:16

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 3'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:49:39', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ae1a88f-495b-4b0f-89fb-6e707a14518b'	System	09 Aug 2020 00:50:05
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 00:50:05

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:49:42', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ae1a88f-495b-4b0f-89fb-6e707a14518b'	System	09 Aug 2020 00:50:05
User entered 'No (N)'	System	09 Aug 2020 00:50:05

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:49:46', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ae1a88f-495b-4b0f-89fb-6e707a14518b'	System	09 Aug 2020 00:50:05
User entered 'No (N)'	System	09 Aug 2020 00:50:05

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:49:50', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ae1a88f-495b-4b0f-89fb-6e707a14518b'	System	09 Aug 2020 00:50:05
User entered 'None (1)'	System	09 Aug 2020 00:50:05

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:49:59', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ae1a88f-495b-4b0f-89fb-6e707a14518b'	System	09 Aug 2020 00:50:05
User entered '08 Aug 2020 20:49'	System	09 Aug 2020 00:50:05

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 4'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:15:39', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'f8237103-27fb-4b1a-9cff-951883c8681f'	System	09 Aug 2020 23:15:58
User entered 'None (1)'	System	09 Aug 2020 23:15:58

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:15:43', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'f8237103-27fb-4b1a-9cff-951883c8681f'	System	09 Aug 2020 23:15:58
User entered 'No (N)'	System	09 Aug 2020 23:15:58

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:15:46', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'f8237103-27fb-4b1a-9cff-951883c8681f'	System	09 Aug 2020 23:15:58
User entered 'No (N)'	System	09 Aug 2020 23:15:58

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:15:48', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'f8237103-27fb-4b1a-9cff-951883c8681f'	System	09 Aug 2020 23:15:58
User entered 'None (1)'	System	09 Aug 2020 23:15:58

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:15:56', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'f8237103-27fb-4b1a-9cff-951883c8681f' User entered '09 Aug 2020 19:15'	System	09 Aug 2020 23:15:58
	System	09 Aug 2020 23:15:58

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 5'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:57:27', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '247f1eb7-9d97-4e8e-a65a-49b4dc194075'	System	10 Aug 2020 22:57:55
User entered 'None (1)'	System	10 Aug 2020 22:57:55

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:57:33', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '247f1eb7-9d97-4e8e-a65a-49b4dc194075'	System	10 Aug 2020 22:57:55
User entered 'No (N)'	System	10 Aug 2020 22:57:55

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:57:37', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '247f1eb7-9d97-4e8e-a65a-49b4dc194075'	System	10 Aug 2020 22:57:55
User entered 'No (N)'	System	10 Aug 2020 22:57:55

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:57:41', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '247f1eb7-9d97-4e8e-a65a-49b4dc194075'	System	10 Aug 2020 22:57:55
User entered 'None (1)'	System	10 Aug 2020 22:57:55

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:57:50', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '247f1eb7-9d97-4e8e-a65a-49b4dc194075'	System	10 Aug 2020 22:57:55
User entered '10 Aug 2020 18:57'	System	10 Aug 2020 22:57:55

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 6'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:53:25', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '25de7148-3f4f-4ba6-b7c9-3e72f458cbc3'	System	12 Aug 2020 00:53:45
User entered 'None (1)'	System	12 Aug 2020 00:53:45

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:53:30', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '25de7148-3f4f-4ba6-b7c9-3e72f458cbc3'	System	12 Aug 2020 00:53:45
User entered 'No (N)'	System	12 Aug 2020 00:53:45

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:53:33', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '25de7148-3f4f-4ba6-b7c9-3e72f458cbc3'	System	12 Aug 2020 00:53:45
User entered 'No (N)'	System	12 Aug 2020 00:53:45

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:53:36', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '25de7148-3f4f-4ba6-b7c9-3e72f458cbc3'	System	12 Aug 2020 00:53:45
User entered 'None (1)'	System	12 Aug 2020 00:53:45

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:53:42', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '25de7148-3f4f-4ba6-b7c9-3e72f458cbc3'	System	12 Aug 2020 00:53:45
User entered '11 Aug 2020 20:53'	System	12 Aug 2020 00:53:45

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 7'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:59:13', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ce7404a-6714-4dca-b871-bea7a212aacf'	System	12 Aug 2020 23:59:42
User entered 'None (1)'	System	12 Aug 2020 23:59:42

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:59:36', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ce7404a-6714-4dca-b871-bea7a212aacf'	System	12 Aug 2020 23:59:42
User entered 'No (N)'	System	12 Aug 2020 23:59:42

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:59:20', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ce7404a-6714-4dca-b871-bea7a212aacf'	System	12 Aug 2020 23:59:42
User entered 'No (N)'	System	12 Aug 2020 23:59:42

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:59:25', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ce7404a-6714-4dca-b871-bea7a212aacf'	System	12 Aug 2020 23:59:42
User entered 'None (1)'	System	12 Aug 2020 23:59:42

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:59:40', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ce7404a-6714-4dca-b871-bea7a212aacf'	System	12 Aug 2020 23:59:42
User entered '12 Aug 2020 19:59'	System	12 Aug 2020 23:59:42

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:39:54', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8a5334ec-1986-4b41-a7c1-3d044e9cea9e'	System	06 Aug 2020 20:40:35
User entered 'None (0)'	System	06 Aug 2020 20:40:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:40:10', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8a5334ec-1986-4b41-a7c1-3d044e9cea9e'	System	06 Aug 2020 20:40:35
User entered 'None (0)'	System	06 Aug 2020 20:40:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:40:14', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8a5334ec-1986-4b41-a7c1-3d044e9cea9e'	System	06 Aug 2020 20:40:35
User entered 'None (0)'	System	06 Aug 2020 20:40:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:40:18', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8a5334ec-1986-4b41-a7c1-3d044e9cea9e'	System	06 Aug 2020 20:40:35
User entered 'None (0)'	System	06 Aug 2020 20:40:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:40:21', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8a5334ec-1986-4b41-a7c1-3d044e9cea9e'	System	06 Aug 2020 20:40:35
User entered 'None (0)'	System	06 Aug 2020 20:40:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:40:24', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8a5334ec-1986-4b41-a7c1-3d044e9cea9e'	System	06 Aug 2020 20:40:35
User entered 'None (0)'	System	06 Aug 2020 20:40:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:40:31', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8a5334ec-1986-4b41-a7c1-3d044e9cea9e'	System	06 Aug 2020 20:40:35
User entered 'No (N)'	System	06 Aug 2020 20:40:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-06T16:40:35', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '8a5334ec-1986-4b41-a7c1-3d044e9cea9e'	System	06 Aug 2020 20:40:35
User entered '06 Aug 2020 16:40'	System	06 Aug 2020 20:40:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '06 Aug 2020 16:33'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '06 Aug 2020 19:03'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '06 Aug 2020 19:58'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 2'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:06:20', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '49699f75-bfef-4a34-8aca-3bbee17a267e'	System	07 Aug 2020 23:06:58
User entered 'None (0)'	System	07 Aug 2020 23:06:58

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:06:25', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '49699f75-bfef-4a34-8aca-3bbee17a267e'	System	07 Aug 2020 23:06:58
User entered 'None (0)'	System	07 Aug 2020 23:06:58

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:06:30', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '49699f75-bfef-4a34-8aca-3bbee17a267e'	System	07 Aug 2020 23:06:58
User entered 'None (0)'	System	07 Aug 2020 23:06:58

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:06:35', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '49699f75-bfef-4a34-8aca-3bbee17a267e'	System	07 Aug 2020 23:06:58
User entered 'None (0)'	System	07 Aug 2020 23:06:58

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:06:38', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '49699f75-bfef-4a34-8aca-3bbee17a267e'	System	07 Aug 2020 23:06:58
User entered 'None (0)'	System	07 Aug 2020 23:06:58

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:06:40', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '49699f75-bfef-4a34-8aca-3bbee17a267e'	System	07 Aug 2020 23:06:58
User entered 'None (0)'	System	07 Aug 2020 23:06:58

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:06:49', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '49699f75-bfef-4a34-8aca-3bbee17a267e'	System	07 Aug 2020 23:06:58
User entered 'No (N)'	System	07 Aug 2020 23:06:58

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-07T19:06:55', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '49699f75-bfef-4a34-8aca-3bbee17a267e'	System	07 Aug 2020 23:06:58
User entered '07 Aug 2020 19:06'	System	07 Aug 2020 23:06:58

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 3'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:50:09', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'c957fa92-9250-42e2-b455-7b35b21badfd'	System	09 Aug 2020 00:50:38
User entered 'None (0)'	System	09 Aug 2020 00:50:38

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:50:12', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'c957fa92-9250-42e2-b455-7b35b21badfd'	System	09 Aug 2020 00:50:38
User entered 'None (0)'	System	09 Aug 2020 00:50:38

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:50:16', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'c957fa92-9250-42e2-b455-7b35b21badfd'	System	09 Aug 2020 00:50:38
User entered 'None (0)'	System	09 Aug 2020 00:50:38

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:50:19', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'c957fa92-9250-42e2-b455-7b35b21badfd'	System	09 Aug 2020 00:50:38
User entered 'None (0)'	System	09 Aug 2020 00:50:38

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:50:22', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'c957fa92-9250-42e2-b455-7b35b21badfd'	System	09 Aug 2020 00:50:38
User entered 'None (0)'	System	09 Aug 2020 00:50:38

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:50:24', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'c957fa92-9250-42e2-b455-7b35b21badfd'	System	09 Aug 2020 00:50:38
User entered 'None (0)'	System	09 Aug 2020 00:50:38

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:50:29', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'c957fa92-9250-42e2-b455-7b35b21badfd'	System	09 Aug 2020 00:50:38
User entered 'No (N)'	System	09 Aug 2020 00:50:38

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-08T20:50:35', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'c957fa92-9250-42e2-b455-7b35b21badfd'	System	09 Aug 2020 00:50:38
User entered '08 Aug 2020 20:50'	System	09 Aug 2020 00:50:38

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 4'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:16:02', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5fb3ebec-c21b-469e-81a3-4d10b53d1497'	System	09 Aug 2020 23:16:35
User entered 'None (0)'	System	09 Aug 2020 23:16:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:16:05', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5fb3ebec-c21b-469e-81a3-4d10b53d1497'	System	09 Aug 2020 23:16:35
User entered 'None (0)'	System	09 Aug 2020 23:16:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:16:12', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5fb3ebec-c21b-469e-81a3-4d10b53d1497'	System	09 Aug 2020 23:16:35
User entered 'None (0)'	System	09 Aug 2020 23:16:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:16:14', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5fb3ebec-c21b-469e-81a3-4d10b53d1497'	System	09 Aug 2020 23:16:35
User entered 'None (0)'	System	09 Aug 2020 23:16:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:16:17', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5fb3ebec-c21b-469e-81a3-4d10b53d1497'	System	09 Aug 2020 23:16:35
User entered 'None (0)'	System	09 Aug 2020 23:16:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:16:19', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5fb3ebec-c21b-469e-81a3-4d10b53d1497'	System	09 Aug 2020 23:16:35
User entered 'None (0)'	System	09 Aug 2020 23:16:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:16:24', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5fb3ebec-c21b-469e-81a3-4d10b53d1497'	System	09 Aug 2020 23:16:35
User entered 'No (N)'	System	09 Aug 2020 23:16:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-09T19:16:30', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5fb3ebec-c21b-469e-81a3-4d10b53d1497'	System	09 Aug 2020 23:16:35
User entered '09 Aug 2020 19:16'	System	09 Aug 2020 23:16:35

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 5'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:57:56', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b04a2a05-dd69-4178-b1e8-a634867d1869'	System	10 Aug 2020 22:58:37
User entered 'None (0)'	System	10 Aug 2020 22:58:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:57:59', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b04a2a05-dd69-4178-b1e8-a634867d1869'	System	10 Aug 2020 22:58:37
User entered 'None (0)'	System	10 Aug 2020 22:58:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:58:05', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b04a2a05-dd69-4178-b1e8-a634867d1869'	System	10 Aug 2020 22:58:37
User entered 'None (0)'	System	10 Aug 2020 22:58:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:58:09', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b04a2a05-dd69-4178-b1e8-a634867d1869' User entered 'None (0)'	System	10 Aug 2020 22:58:37
	System	10 Aug 2020 22:58:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:58:13', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b04a2a05-dd69-4178-b1e8-a634867d1869'	System	10 Aug 2020 22:58:37
User entered 'None (0)'	System	10 Aug 2020 22:58:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:58:16', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b04a2a05-dd69-4178-b1e8-a634867d1869'	System	10 Aug 2020 22:58:37
User entered 'None (0)'	System	10 Aug 2020 22:58:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:58:26', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b04a2a05-dd69-4178-b1e8-a634867d1869'	System	10 Aug 2020 22:58:37
User entered 'No (N)'	System	10 Aug 2020 22:58:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-10T18:58:33', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b04a2a05-dd69-4178-b1e8-a634867d1869'	System	10 Aug 2020 22:58:37
User entered '10 Aug 2020 18:58'	System	10 Aug 2020 22:58:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 6'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:53:48', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '52b08568-b725-495b-984a-bd9ec41d105a'	System	12 Aug 2020 00:54:47
User entered 'None (0)'	System	12 Aug 2020 00:54:47

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:54:06', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '52b08568-b725-495b-984a-bd9ec41d105a'	System	12 Aug 2020 00:54:47
User entered 'None (0)'	System	12 Aug 2020 00:54:47

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:54:17', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '52b08568-b725-495b-984a-bd9ec41d105a'	System	12 Aug 2020 00:54:47
User entered 'None (0)'	System	12 Aug 2020 00:54:47

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:54:20', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '52b08568-b725-495b-984a-bd9ec41d105a'	System	12 Aug 2020 00:54:47
User entered 'None (0)'	System	12 Aug 2020 00:54:47

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:54:25', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '52b08568-b725-495b-984a-bd9ec41d105a'	System	12 Aug 2020 00:54:47
User entered 'None (0)'	System	12 Aug 2020 00:54:47

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:54:28', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '52b08568-b725-495b-984a-bd9ec41d105a'	System	12 Aug 2020 00:54:47
User entered 'None (0)'	System	12 Aug 2020 00:54:47

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:54:38', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '52b08568-b725-495b-984a-bd9ec41d105a'	System	12 Aug 2020 00:54:47
User entered 'No (N)'	System	12 Aug 2020 00:54:47

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-11T20:54:45', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '52b08568-b725-495b-984a-bd9ec41d105a'	System	12 Aug 2020 00:54:47
User entered '11 Aug 2020 20:54'	System	12 Aug 2020 00:54:47

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 7'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:59:46', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '50998a24-9efe-4219-88b8-971fe2d9ab7d'	System	13 Aug 2020 00:00:37
User entered 'None (0)'	System	13 Aug 2020 00:00:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:59:49', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '50998a24-9efe-4219-88b8-971fe2d9ab7d'	System	13 Aug 2020 00:00:37
User entered 'None (0)'	System	13 Aug 2020 00:00:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:59:53', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '50998a24-9efe-4219-88b8-971fe2d9ab7d'	System	13 Aug 2020 00:00:37
User entered 'None (0)'	System	13 Aug 2020 00:00:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T19:59:57', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '50998a24-9efe-4219-88b8-971fe2d9ab7d'	System	13 Aug 2020 00:00:37
User entered 'None (0)'	System	13 Aug 2020 00:00:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T20:00:01', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '50998a24-9efe-4219-88b8-971fe2d9ab7d'	System	13 Aug 2020 00:00:37
User entered 'None (0)'	System	13 Aug 2020 00:00:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T20:00:04', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '50998a24-9efe-4219-88b8-971fe2d9ab7d'	System	13 Aug 2020 00:00:37
User entered 'None (0)'	System	13 Aug 2020 00:00:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T20:00:15', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '50998a24-9efe-4219-88b8-971fe2d9ab7d'	System	13 Aug 2020 00:00:37
User entered 'No (N)'	System	13 Aug 2020 00:00:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32887018fb7001e)', Time: '2020-08-12T20:00:21', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '50998a24-9efe-4219-88b8-971fe2d9ab7d'	System	13 Aug 2020 00:00:37
User entered '12 Aug 2020 20:00'	System	13 Aug 2020 00:00:37

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 20:23:30

US3202042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:15:36
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	13 Aug 2020 21:38:21

US3202042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:15:36
User entered '13 Aug 2020'	Lilian Nukuna (b) (4) (b) (4)	13 Aug 2020 21:38:21

US3202042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:15:36
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	13 Aug 2020 21:38:21

US3202042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:15:36
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	13 Aug 2020 21:38:21

US3202042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:15:52
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	10 Sep 2020 20:01:29

US3202042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'I'	System	10 Sep 2020 20:01:29

US3202042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:14:22
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:21:54

US3202042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:14:34
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:14:22
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date contact made' (Site from System).	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:22:02
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Sep 2020 16:21:54
User entered '28 Aug 2020'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:21:54

US3202042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:14:22
User entered 'Contact Made (CONTACT MADE)'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:21:54

US3202042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:14:22
User entered empty.	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:21:54

US3202042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:14:38
User closed query 'per source safety call 28Aug20, please verify and update.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 14:42:07
Query 'per source safety call 28Aug20, please verify and update.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4) (b) (4)	22 Sep 2020 17:00:43
User opened query 'per source safety call 28Aug20, please verify and update.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 16:17:11
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	10 Sep 2020 20:01:44

US3202042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'I'	System	10 Sep 2020 20:01:44

US3202042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:15:24
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:03:04

US3202042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:15:24
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 13:33:21
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'subject missed a number of phone calls and would call back afterwards. Contacts were made' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:06:47
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Sep 2020 15:03:04
User entered '3 Sep 2020'	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:03:04

US3202042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:15:24
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:03:04

US3202042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:15:24
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:03:04

US3202042

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:17:31
User closed query 'per source 03Sep20, please verify and update' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 16:19:36
Query 'per source 03Sep20, please verify and update' answered with 'yes, subject did receive the second dose of the vaccine on the 10th of September' (Site from CRA).	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:01:17
User opened query 'per source 03Sep20, please verify and update' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 16:17:54
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	10 Sep 2020 20:02:15

US3202042

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'I'	System	10 Sep 2020 20:02:15

US3202042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:18:34
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	10 Sep 2020 20:02:26

US3202042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:18:34
User entered '10 Sep 2020'	Erica Osmundsen (b) (4)	10 Sep 2020 20:02:26

US3202042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:18:34
User entered 'Clinic (Clinic)'	Erica Osmundsen (b) (4)	10 Sep 2020 20:02:26

US3202042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'VISIT2'	System	10 Sep 2020 20:02:26

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4)	30 Sep 2020 14:45:35
	(b) (4)	

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User closed query 'please complete' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 20:36:02
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:53:23
Query 'please complete' answered with 'updated' (Site from CRA).	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:46
User opened query 'please complete' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 18:25:22

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Sep 2020 14:53:23
User entered '10 Sep 2020' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:53:23
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Sep 2020 14:45:35
User entered '04 Sep 2020'	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered '15:03' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Sep 2020 14:53:23
User entered '09:33'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '10 Sep 2020 15:03'	System	30 Sep 2020 14:53:23
User entered '04 Sep 2020 09:33'	System	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered '36.9' C reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:53:23
User entered '36.6' C	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered '69' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Sep 2020 14:53:23
User entered '72'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'bpm'	System	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered '12' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Sep 2020 14:53:23
User entered '16'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'breaths/min'	System	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered '128' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Sep 2020 14:53:23
User entered '119'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'mmHg'	System	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered '88' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Sep 2020 14:53:23
User entered '66'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'mmHg'	System	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Sep 2020 14:54:06
User entered '10 Sep 2020' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:54:06
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Sep 2020 14:45:35
User entered '04 Sep 2020'	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	30 Sep 2020 14:54:06
User entered '16:25' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:54:06
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	30 Sep 2020 14:53:23
User entered '10:46'	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '10 Sep 2020 16:25'	System	30 Sep 2020 14:54:06
User entered '04 Sep 2020 10:46'	System	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered '36.9' C reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:54:06
User entered '36.7' C	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered '67' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Sep 2020 14:54:06
User entered '66'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'bpm'	System	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered '16'	zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'breaths/min'	System	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered '135' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Sep 2020 14:54:06
User entered '128'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'mmHg'	System	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:16
User entered '89' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Sep 2020 14:54:06
User entered '83'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'mmHg'	System	30 Sep 2020 14:45:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:25:30
User entered 'No (N)'	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:20:28

US3202042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:25:30
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:20:28

US3202042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:25:47
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	10 Sep 2020 20:02:52

US3202042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:25:47
User entered empty.	Erica Osmundsen (b) (4)	10 Sep 2020 20:02:52

US3202042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

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)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:25:47
User entered empty.	Erica Osmundsen (b) (4)	10 Sep 2020 20:02:52

US3202042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 20:02:52

US3202042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:25:47
User entered '10 Sep 2020'	Erica Osmundsen (b) (4)	10 Sep 2020 20:02:52

US3202042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:25:47
User entered '15:42'	Erica Osmundsen (b) (4)	10 Sep 2020 20:02:52

US3202042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '10 Sep 2020 15:42'	System	10 Sep 2020 20:02:52

US3202042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:25:47
User entered 'Left Arm (LEFT ARM)'	Erica Osmundsen (b) (4)	10 Sep 2020 20:02:52

US3202042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:25:47
User entered 'ONCE'	System	10 Sep 2020 20:02:52

US3202042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 20:02:52

US3202042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:26:14
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:45:28

US3202042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:26:14
User entered '10 Sep 2020'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:45:28

US3202042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:26:14
User entered '15:12'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:45:28

US3202042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '10 Sep 2020 15:12'	System	22 Sep 2020 16:45:28

US3202042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:41:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:26:23
User entered '10 Sep 2020'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:45:46

US3202042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:45:46

US3202042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:26:23
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:45:46

US3202042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:24

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:26:23
User entered '15:11'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:45:46

US3202042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '10 Sep 2020 15:11'	System	22 Sep 2020 16:45:46

US3202042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:45:46

US3202042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:26:23
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:45:46

US3202042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:26:23
User entered empty.	zackery harmon (b) (4) (b) (4)	22 Sep 2020 16:45:46

US3202042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered empty.	System	22 Sep 2020 16:45:46

US3202042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:26:40
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:20:35

US3202042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'I'	System	17 Sep 2020 15:20:35

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:20:22', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '558c0832-51af-4290-a7a9-d79fcc563b37'	System	10 Sep 2020 20:20:38
User entered 'Yes (Y)'	System	10 Sep 2020 20:20:38

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:20:27', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '558c0832-51af-4290-a7a9-d79fcc563b37'	System	10 Sep 2020 20:20:38
User entered '98.5'	System	10 Sep 2020 20:20:38

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:20:31', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '558c0832-51af-4290-a7a9-d79fcc563b37'	System	10 Sep 2020 20:20:38
User entered 'No (N)'	System	10 Sep 2020 20:20:38

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:20:34', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '558c0832-51af-4290-a7a9-d79fcc563b37'	System	10 Sep 2020 20:20:38
User entered '10 Sep 2020 16:20'	System	10 Sep 2020 20:20:38

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Sep 2020 16:02'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Sep 2020 18:32'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:55:05', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'ddf8f21e-9092-4284-98e6-898575b508bc'	System	11 Sep 2020 00:55:26
User entered 'Yes (Y)'	System	11 Sep 2020 00:55:26

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:55:13', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'ddf8f21e-9092-4284-98e6-898575b508bc'	System	11 Sep 2020 00:55:26
User entered '98.0'	System	11 Sep 2020 00:55:26

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:55:17', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'ddf8f21e-9092-4284-98e6-898575b508bc'	System	11 Sep 2020 00:55:26
User entered 'No (N)'	System	11 Sep 2020 00:55:26

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:55:22', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'ddf8f21e-9092-4284-98e6-898575b508bc'	System	11 Sep 2020 00:55:26
User entered '10 Sep 2020 20:55'	System	11 Sep 2020 00:55:26

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Sep 2020 19:27'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 2'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:00:01', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '45c6c8a8-82b2-4200-aff-225191352b98'	System	12 Sep 2020 00:00:20
User entered 'Yes (Y)'	System	12 Sep 2020 00:00:20

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:00:10', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '45c6c8a8-82b2-4200-aff-225191352b98'	System	12 Sep 2020 00:00:20
User entered '100.0'	System	12 Sep 2020 00:00:20

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:00:13', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '45c6c8a8-82b2-4200-aff-225191352b98'	System	12 Sep 2020 00:00:20
User entered 'No (N)'	System	12 Sep 2020 00:00:20

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:00:19', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '45c6c8a8-82b2-4200-aff-225191352b98'	System	12 Sep 2020 00:00:20
User entered '11 Sep 2020 20:00'	System	12 Sep 2020 00:00:20

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 3'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:51:56', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '95cbc732-e8e6-419e-aa4e-9ff0ff307dfb'	System	13 Sep 2020 01:52:19
User entered 'Yes (Y)'	System	13 Sep 2020 01:52:19

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:09', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '95cbc732-e8e6-419e-aa4e-9ff0ff307dfb'	System	13 Sep 2020 01:52:19
User entered '98.0'	System	13 Sep 2020 01:52:19

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:13', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '95cbc732-e8e6-419e-aa4e-9ff0ff307dfb'	System	13 Sep 2020 01:52:19
User entered 'No (N)'	System	13 Sep 2020 01:52:19

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:17', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '95cbc732-e8e6-419e-aa4e-9ff0ff307dfb'	System	13 Sep 2020 01:52:19
User entered '12 Sep 2020 21:52'	System	13 Sep 2020 01:52:19

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 4'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T18:59:43', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '608ab658-cf41-497d-ac13-bf20f46c7df2'	System	13 Sep 2020 22:59:57
User entered 'Yes (Y)'	System	13 Sep 2020 22:59:57

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T18:59:48', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '608ab658-cf41-497d-ac13-bf20f46c7df2'	System	13 Sep 2020 22:59:57
User entered '98.2'	System	13 Sep 2020 22:59:57

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T18:59:52', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '608ab658-cf41-497d-ac13-bf20f46c7df2'	System	13 Sep 2020 22:59:57
User entered 'No (N)'	System	13 Sep 2020 22:59:57

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T18:59:55', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '608ab658-cf41-497d-ac13-bf20f46c7df2'	System	13 Sep 2020 22:59:57
User entered '13 Sep 2020 18:59'	System	13 Sep 2020 22:59:57

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 5'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:41:38', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd7cee5cd-465f-4ab6-8407-e9e83e7725ed'	System	14 Sep 2020 21:42:00
User entered 'Yes (Y)'	System	14 Sep 2020 21:42:00

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:41:48', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd7cee5cd-465f-4ab6-8407-e9e83e7725ed'	System	14 Sep 2020 21:42:00
User entered '98.0'	System	14 Sep 2020 21:42:00

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:41:51', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd7cee5cd-465f-4ab6-8407-e9e83e7725ed'	System	14 Sep 2020 21:42:00
User entered 'No (N)'	System	14 Sep 2020 21:42:00

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:41:59', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd7cee5cd-465f-4ab6-8407-e9e83e7725ed'	System	14 Sep 2020 21:42:00
User entered '14 Sep 2020 17:41'	System	14 Sep 2020 21:42:00

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 6'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:16:58', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '293adb14-1fe6-434c-af75-d7ae16b038fa'	System	15 Sep 2020 17:17:20
User entered 'Yes (Y)'	System	15 Sep 2020 17:17:20

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:08', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '293adb14-1fe6-434c-af75-d7ae16b038fa'	System	15 Sep 2020 17:17:20
User entered '98.0'	System	15 Sep 2020 17:17:20

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:11', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '293adb14-1fe6-434c-af75-d7ae16b038fa'	System	15 Sep 2020 17:17:20
User entered 'No (N)'	System	15 Sep 2020 17:17:20

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:14', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '293adb14-1fe6-434c-af75-d7ae16b038fa'	System	15 Sep 2020 17:17:20
User entered '15 Sep 2020 13:17'	System	15 Sep 2020 17:17:20

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 7'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:17', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0e60e811-fc77-4ea4-912f-22f75ccab04d'	System	17 Sep 2020 08:33:30
User entered 'Yes (Y)'	System	17 Sep 2020 08:33:30

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:22', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0e60e811-fc77-4ea4-912f-22f75ccab04d'	System	17 Sep 2020 08:33:30
User entered '98.2'	System	17 Sep 2020 08:33:30

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:25', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0e60e811-fc77-4ea4-912f-22f75ccab04d'	System	17 Sep 2020 08:33:30
User entered 'No (N)'	System	17 Sep 2020 08:33:30

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:29', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0e60e811-fc77-4ea4-912f-22f75ccab04d'	System	17 Sep 2020 08:33:30
User entered '17 Sep 2020 04:33'	System	17 Sep 2020 08:33:30

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:14:24', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '6aafbb3e-ae90-4080-8658-429572444448'	System	10 Sep 2020 20:15:07
User entered 'None (1)'	System	10 Sep 2020 20:15:07

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:14:41', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '6aafbb3e-ae90-4080-8658-429572444448'	System	10 Sep 2020 20:15:07
User entered 'No (N)'	System	10 Sep 2020 20:15:07

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:14:46', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '6aafbb3e-ae90-4080-8658-429572444448'	System	10 Sep 2020 20:15:07
User entered 'No (N)'	System	10 Sep 2020 20:15:07

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:14:50', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '6aafbb3e-ae90-4080-8658-429572444448'	System	10 Sep 2020 20:15:07
User entered 'None (1)'	System	10 Sep 2020 20:15:07

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:14:58', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '6aafbb3e-ae90-4080-8658-429572444448'	System	10 Sep 2020 20:15:07
User entered '10 Sep 2020 16:14'	System	10 Sep 2020 20:15:07

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Sep 2020 16:02'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Sep 2020 18:32'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:55:34', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0c2de5f7-2f37-47b7-b656-10fc7c25f9d8'	System	11 Sep 2020 00:56:05
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 00:56:05

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:55:38', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0c2de5f7-2f37-47b7-b656-10fc7c25f9d8'	System	11 Sep 2020 00:56:05
User entered 'No (N)'	System	11 Sep 2020 00:56:05

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:55:42', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0c2de5f7-2f37-47b7-b656-10fc7c25f9d8'	System	11 Sep 2020 00:56:05
User entered 'No (N)'	System	11 Sep 2020 00:56:05

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:55:46', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0c2de5f7-2f37-47b7-b656-10fc7c25f9d8'	System	11 Sep 2020 00:56:05
User entered 'None (1)'	System	11 Sep 2020 00:56:05

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:56:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0c2de5f7-2f37-47b7-b656-10fc7c25f9d8'	System	11 Sep 2020 00:56:05
User entered '10 Sep 2020 20:56'	System	11 Sep 2020 00:56:05

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Sep 2020 19:27'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 2'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:00:37', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0cb84e9d-16c1-4684-a8bc-7386a027eec4'	System	12 Sep 2020 00:01:21
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 00:01:21

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:00:42', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0cb84e9d-16c1-4684-a8bc-7386a027eec4'	System	12 Sep 2020 00:01:21
User entered 'No (N)'	System	12 Sep 2020 00:01:21

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:01:01', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0cb84e9d-16c1-4684-a8bc-7386a027eec4'	System	12 Sep 2020 00:01:21
User entered 'No (N)'	System	12 Sep 2020 00:01:21

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:01:08', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0cb84e9d-16c1-4684-a8bc-7386a027eec4'	System	12 Sep 2020 00:01:21
User entered 'None (1)'	System	12 Sep 2020 00:01:21

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:01:17', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0cb84e9d-16c1-4684-a8bc-7386a027eec4'	System	12 Sep 2020 00:01:21
User entered '11 Sep 2020 20:01'	System	12 Sep 2020 00:01:21

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 3'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:22', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'edafde54-b484-45e3-b4fb-b557e1ead424'	System	13 Sep 2020 01:52:40
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 01:52:40

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:26', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'edafde54-b484-45e3-b4fb-b557e1ead424'	System	13 Sep 2020 01:52:40
User entered 'No (N)'	System	13 Sep 2020 01:52:40

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:29', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'edafde54-b484-45e3-b4fb-b557e1ead424'	System	13 Sep 2020 01:52:40
User entered 'No (N)'	System	13 Sep 2020 01:52:40

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:31', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'edafde54-b484-45e3-b4fb-b557e1ead424'	System	13 Sep 2020 01:52:40
User entered 'None (1)'	System	13 Sep 2020 01:52:40

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:38', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'edafde54-b484-45e3-b4fb-b557e1ead424'	System	13 Sep 2020 01:52:40
User entered '12 Sep 2020 21:52'	System	13 Sep 2020 01:52:40

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 4'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb3eb0a7-c99b-49d4-b191-88624ece2d06'	System	13 Sep 2020 23:00:16
User entered 'None (1)'	System	13 Sep 2020 23:00:16

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:04', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb3eb0a7-c99b-49d4-b191-88624ece2d06'	System	13 Sep 2020 23:00:16
User entered 'No (N)'	System	13 Sep 2020 23:00:16

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:07', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb3eb0a7-c99b-49d4-b191-88624ece2d06'	System	13 Sep 2020 23:00:16
User entered 'No (N)'	System	13 Sep 2020 23:00:16

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:10', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb3eb0a7-c99b-49d4-b191-88624ece2d06'	System	13 Sep 2020 23:00:16
User entered 'None (1)'	System	13 Sep 2020 23:00:16

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:14', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb3eb0a7-c99b-49d4-b191-88624ece2d06'	System	13 Sep 2020 23:00:16
User entered '13 Sep 2020 19:00'	System	13 Sep 2020 23:00:16

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 5'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:42:41', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '55b70974-fe02-4f02-9554-b1fe9294d0a6'	System	14 Sep 2020 21:42:51
User entered 'None (1)'	System	14 Sep 2020 21:42:51

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:42:23', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '55b70974-fe02-4f02-9554-b1fe9294d0a6'	System	14 Sep 2020 21:42:51
User entered 'No (N)'	System	14 Sep 2020 21:42:51

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:42:27', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '55b70974-fe02-4f02-9554-b1fe9294d0a6'	System	14 Sep 2020 21:42:51
User entered 'No (N)'	System	14 Sep 2020 21:42:51

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:42:30', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '55b70974-fe02-4f02-9554-b1fe9294d0a6'	System	14 Sep 2020 21:42:51
User entered 'None (1)'	System	14 Sep 2020 21:42:51

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:42:48', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '55b70974-fe02-4f02-9554-b1fe9294d0a6'	System	14 Sep 2020 21:42:51
User entered '14 Sep 2020 17:42'	System	14 Sep 2020 21:42:51

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 6'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:19', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a11d80c6-5f8c-4c6f-9ccb-215725740adf'	System	15 Sep 2020 17:17:36
User entered 'None (1)'	System	15 Sep 2020 17:17:36

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:24', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a11d80c6-5f8c-4c6f-9ccb-215725740adf'	System	15 Sep 2020 17:17:36
User entered 'No (N)'	System	15 Sep 2020 17:17:36

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:28', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a11d80c6-5f8c-4c6f-9ccb-215725740adf'	System	15 Sep 2020 17:17:36
User entered 'No (N)'	System	15 Sep 2020 17:17:36

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:32', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a11d80c6-5f8c-4c6f-9ccb-215725740adf'	System	15 Sep 2020 17:17:36
User entered 'None (1)'	System	15 Sep 2020 17:17:36

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:35', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a11d80c6-5f8c-4c6f-9ccb-215725740adf'	System	15 Sep 2020 17:17:36
User entered '15 Sep 2020 13:17'	System	15 Sep 2020 17:17:36

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 7'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:33', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b40b03b6-4bdb-4596-ad96-034f2ccaa431'	System	17 Sep 2020 08:33:46
User entered 'None (1)'	System	17 Sep 2020 08:33:46

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:36', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b40b03b6-4bdb-4596-ad96-034f2ccaa431'	System	17 Sep 2020 08:33:46
User entered 'No (N)'	System	17 Sep 2020 08:33:46

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:39', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b40b03b6-4bdb-4596-ad96-034f2ccaa431'	System	17 Sep 2020 08:33:46
User entered 'No (N)'	System	17 Sep 2020 08:33:46

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:42', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b40b03b6-4bdb-4596-ad96-034f2ccaa431'	System	17 Sep 2020 08:33:46
User entered 'None (1)'	System	17 Sep 2020 08:33:46

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:45', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b40b03b6-4bdb-4596-ad96-034f2ccaa431'	System	17 Sep 2020 08:33:46
User entered '17 Sep 2020 04:33'	System	17 Sep 2020 08:33:46

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:15:05', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b68c5413-846e-4b1f-b681-e1cc7cccb36b'	System	10 Sep 2020 20:15:47
User entered 'None (0)'	System	10 Sep 2020 20:15:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:15:13', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b68c5413-846e-4b1f-b681-e1cc7cccb36b'	System	10 Sep 2020 20:15:47
User entered 'None (0)'	System	10 Sep 2020 20:15:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:15:19', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b68c5413-846e-4b1f-b681-e1cc7cccb36b'	System	10 Sep 2020 20:15:47
User entered 'None (0)'	System	10 Sep 2020 20:15:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:15:24', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b68c5413-846e-4b1f-b681-e1cc7cccb36b'	System	10 Sep 2020 20:15:47
User entered 'None (0)'	System	10 Sep 2020 20:15:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:15:29', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b68c5413-846e-4b1f-b681-e1cc7cccb36b'	System	10 Sep 2020 20:15:47
User entered 'None (0)'	System	10 Sep 2020 20:15:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:15:33', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b68c5413-846e-4b1f-b681-e1cc7cccb36b'	System	10 Sep 2020 20:15:47
User entered 'None (0)'	System	10 Sep 2020 20:15:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:15:37', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b68c5413-846e-4b1f-b681-e1cc7cccb36b'	System	10 Sep 2020 20:15:47
User entered 'No (N)'	System	10 Sep 2020 20:15:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T16:15:43', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b68c5413-846e-4b1f-b681-e1cc7cccb36b'	System	10 Sep 2020 20:15:47
User entered '10 Sep 2020 16:15'	System	10 Sep 2020 20:15:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Sep 2020 16:02'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Sep 2020 18:32'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:56:11', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '3e7e76c7-4922-4966-b48b-25726127f008'	System	11 Sep 2020 00:56:47
User entered 'None (0)'	System	11 Sep 2020 00:56:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:56:15', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '3e7e76c7-4922-4966-b48b-25726127f008'	System	11 Sep 2020 00:56:47
User entered 'None (0)'	System	11 Sep 2020 00:56:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:56:20', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '3e7e76c7-4922-4966-b48b-25726127f008'	System	11 Sep 2020 00:56:47
User entered 'None (0)'	System	11 Sep 2020 00:56:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:56:27', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '3e7e76c7-4922-4966-b48b-25726127f008'	System	11 Sep 2020 00:56:47
User entered 'None (0)'	System	11 Sep 2020 00:56:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:56:30', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '3e7e76c7-4922-4966-b48b-25726127f008'	System	11 Sep 2020 00:56:47
User entered 'None (0)'	System	11 Sep 2020 00:56:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:56:33', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '3e7e76c7-4922-4966-b48b-25726127f008'	System	11 Sep 2020 00:56:47
User entered 'None (0)'	System	11 Sep 2020 00:56:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:56:37', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '3e7e76c7-4922-4966-b48b-25726127f008'	System	11 Sep 2020 00:56:47
User entered 'No (N)'	System	11 Sep 2020 00:56:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-10T20:56:42', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '3e7e76c7-4922-4966-b48b-25726127f008'	System	11 Sep 2020 00:56:47
User entered '10 Sep 2020 20:56'	System	11 Sep 2020 00:56:47

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '10 Sep 2020 19:27'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 2'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:01:33', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'e57f9d02-9a49-4b12-ae1e-f75a0a89bb86'	System	12 Sep 2020 00:02:13
User entered 'None (0)'	System	12 Sep 2020 00:02:13

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:01:38', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'e57f9d02-9a49-4b12-ae1e-f75a0a89bb86'	System	12 Sep 2020 00:02:13
User entered 'None (0)'	System	12 Sep 2020 00:02:13

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:01:44', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'e57f9d02-9a49-4b12-ae1e-f75a0a89bb86'	System	12 Sep 2020 00:02:13
User entered 'None (0)'	System	12 Sep 2020 00:02:13

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:01:47', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'e57f9d02-9a49-4b12-ae1e-f75a0a89bb86'	System	12 Sep 2020 00:02:13
User entered 'None (0)'	System	12 Sep 2020 00:02:13

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:01:51', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'e57f9d02-9a49-4b12-ae1e-f75a0a89bb86'	System	12 Sep 2020 00:02:13
User entered 'None (0)'	System	12 Sep 2020 00:02:13

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:01:54', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'e57f9d02-9a49-4b12-ae1e-f75a0a89bb86'	System	12 Sep 2020 00:02:13
User entered 'None (0)'	System	12 Sep 2020 00:02:13

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:01:58', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'e57f9d02-9a49-4b12-ae1e-f75a0a89bb86'	System	12 Sep 2020 00:02:13
User entered 'No (N)'	System	12 Sep 2020 00:02:13

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-11T20:02:10', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'e57f9d02-9a49-4b12-ae1e-f75a0a89bb86'	System	12 Sep 2020 00:02:13
User entered '11 Sep 2020 20:02'	System	12 Sep 2020 00:02:13

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 3'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:43', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb6d4e87-258e-4b8a-966f-bebe72e988f2'	System	13 Sep 2020 01:53:07
User entered 'None (0)'	System	13 Sep 2020 01:53:07

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:46', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb6d4e87-258e-4b8a-966f-bebe72e988f2'	System	13 Sep 2020 01:53:07
User entered 'None (0)'	System	13 Sep 2020 01:53:07

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:49', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb6d4e87-258e-4b8a-966f-bebe72e988f2'	System	13 Sep 2020 01:53:07
User entered 'None (0)'	System	13 Sep 2020 01:53:07

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:52', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb6d4e87-258e-4b8a-966f-bebe72e988f2'	System	13 Sep 2020 01:53:07
User entered 'None (0)'	System	13 Sep 2020 01:53:07

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:54', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb6d4e87-258e-4b8a-966f-bebe72e988f2'	System	13 Sep 2020 01:53:07
User entered 'None (0)'	System	13 Sep 2020 01:53:07

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:52:57', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb6d4e87-258e-4b8a-966f-bebe72e988f2'	System	13 Sep 2020 01:53:07
User entered 'None (0)'	System	13 Sep 2020 01:53:07

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:53:01', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb6d4e87-258e-4b8a-966f-bebe72e988f2'	System	13 Sep 2020 01:53:07
User entered 'No (N)'	System	13 Sep 2020 01:53:07

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-12T21:53:04', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bb6d4e87-258e-4b8a-966f-bebe72e988f2'	System	13 Sep 2020 01:53:07
User entered '12 Sep 2020 21:53'	System	13 Sep 2020 01:53:07

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 4'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:19', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '475609e8-a9ac-45bf-b8ca-97b44bfc476f'	System	13 Sep 2020 23:00:50
User entered 'None (0)'	System	13 Sep 2020 23:00:50

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:22', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '475609e8-a9ac-45bf-b8ca-97b44bfc476f'	System	13 Sep 2020 23:00:50
User entered 'None (0)'	System	13 Sep 2020 23:00:50

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:25', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '475609e8-a9ac-45bf-b8ca-97b44bfc476f' User entered 'None (0)'	System	13 Sep 2020 23:00:50
	System	13 Sep 2020 23:00:50

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:29', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '475609e8-a9ac-45bf-b8ca-97b44bfc476f' User entered 'None (0)'	System	13 Sep 2020 23:00:50
	System	13 Sep 2020 23:00:50

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:33', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '475609e8-a9ac-45bf-b8ca-97b44bfc476f'	System	13 Sep 2020 23:00:50
User entered 'None (0)'	System	13 Sep 2020 23:00:50

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:36', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '475609e8-a9ac-45bf-b8ca-97b44bfc476f' User entered 'None (0)'	System	13 Sep 2020 23:00:50
	System	13 Sep 2020 23:00:50

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:46', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '475609e8-a9ac-45bf-b8ca-97b44bfc476f'	System	13 Sep 2020 23:00:50
User entered 'No (N)'	System	13 Sep 2020 23:00:50

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-13T19:00:49', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '475609e8-a9ac-45bf-b8ca-97b44bfc476f'	System	13 Sep 2020 23:00:50
User entered '13 Sep 2020 19:00'	System	13 Sep 2020 23:00:50

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 5'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:42:55', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '77ca048b-f450-4bd5-a0ce-c91eb44b085d'	System	14 Sep 2020 21:43:25
User entered 'None (0)'	System	14 Sep 2020 21:43:25

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:42:59', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '77ca048b-f450-4bd5-a0ce-c91eb44b085d'	System	14 Sep 2020 21:43:25
User entered 'None (0)'	System	14 Sep 2020 21:43:25

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:43:02', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '77ca048b-f450-4bd5-a0ce-c91eb44b085d'	System	14 Sep 2020 21:43:25
User entered 'None (0)'	System	14 Sep 2020 21:43:25

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:43:05', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '77ca048b-f450-4bd5-a0ce-c91eb44b085d'	System	14 Sep 2020 21:43:25
User entered 'None (0)'	System	14 Sep 2020 21:43:25

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:43:09', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '77ca048b-f450-4bd5-a0ce-c91eb44b085d'	System	14 Sep 2020 21:43:25
User entered 'None (0)'	System	14 Sep 2020 21:43:25

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:43:12', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '77ca048b-f450-4bd5-a0ce-c91eb44b085d'	System	14 Sep 2020 21:43:25
User entered 'None (0)'	System	14 Sep 2020 21:43:25

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:43:18', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '77ca048b-f450-4bd5-a0ce-c91eb44b085d'	System	14 Sep 2020 21:43:25
User entered 'No (N)'	System	14 Sep 2020 21:43:25

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-14T17:43:23', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '77ca048b-f450-4bd5-a0ce-c91eb44b085d'	System	14 Sep 2020 21:43:25
User entered '14 Sep 2020 17:43'	System	14 Sep 2020 21:43:25

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 6'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:40', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '97c95006-da61-4fb7-afd6-97cb0dd18f2a'	System	15 Sep 2020 17:18:09
User entered 'None (0)'	System	15 Sep 2020 17:18:09

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:43', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '97c95006-da61-4fb7-afd6-97cb0dd18f2a'	System	15 Sep 2020 17:18:09
User entered 'None (0)'	System	15 Sep 2020 17:18:09

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:45', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '97c95006-da61-4fb7-afd6-97cb0dd18f2a'	System	15 Sep 2020 17:18:09
User entered 'None (0)'	System	15 Sep 2020 17:18:09

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:47', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '97c95006-da61-4fb7-afd6-97cb0dd18f2a'	System	15 Sep 2020 17:18:09
User entered 'None (0)'	System	15 Sep 2020 17:18:09

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:50', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '97c95006-da61-4fb7-afd6-97cb0dd18f2a'	System	15 Sep 2020 17:18:09
User entered 'None (0)'	System	15 Sep 2020 17:18:09

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:52', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '97c95006-da61-4fb7-afd6-97cb0dd18f2a'	System	15 Sep 2020 17:18:09
User entered 'None (0)'	System	15 Sep 2020 17:18:09

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:17:56', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '97c95006-da61-4fb7-afd6-97cb0dd18f2a'	System	15 Sep 2020 17:18:09
User entered 'No (N)'	System	15 Sep 2020 17:18:09

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-15T13:18:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '97c95006-da61-4fb7-afd6-97cb0dd18f2a'	System	15 Sep 2020 17:18:09
User entered '15 Sep 2020 13:18'	System	15 Sep 2020 17:18:09

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	10 Sep 2020 20:02:52
User entered 'Day 7'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:49', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5cfd1995-c8bd-4e76-a168-d832678526ab'	System	17 Sep 2020 08:34:12
User entered 'None (0)'	System	17 Sep 2020 08:34:12

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:51', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5cfd1995-c8bd-4e76-a168-d832678526ab'	System	17 Sep 2020 08:34:12
User entered 'None (0)'	System	17 Sep 2020 08:34:12

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:54', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5cfd1995-c8bd-4e76-a168-d832678526ab'	System	17 Sep 2020 08:34:12
User entered 'None (0)'	System	17 Sep 2020 08:34:12

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:56', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5cfd1995-c8bd-4e76-a168-d832678526ab'	System	17 Sep 2020 08:34:12
User entered 'None (0)'	System	17 Sep 2020 08:34:12

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:33:59', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5cfd1995-c8bd-4e76-a168-d832678526ab'	System	17 Sep 2020 08:34:12
User entered 'None (0)'	System	17 Sep 2020 08:34:12

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:34:01', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5cfd1995-c8bd-4e76-a168-d832678526ab'	System	17 Sep 2020 08:34:12
User entered 'None (0)'	System	17 Sep 2020 08:34:12

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:34:05', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5cfd1995-c8bd-4e76-a168-d832678526ab'	System	17 Sep 2020 08:34:12
User entered 'No (N)'	System	17 Sep 2020 08:34:12

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-09-17T04:34:08', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5cfd1995-c8bd-4e76-a168-d832678526ab'	System	17 Sep 2020 08:34:12
User entered '17 Sep 2020 04:34'	System	17 Sep 2020 08:34:12

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:02:52

US3202042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:02:52

US3202042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:28:02
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:22:18

US3202042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:28:02
User entered '17 Sep 2020'	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:22:18

US3202042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:28:02
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:22:18

US3202042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:28:02
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:22:18

US3202042

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:56:17
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	17 Sep 2020 15:22:28

US3202042

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'I'	System	17 Sep 2020 15:22:28

US3202042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:19:02
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 17:21:27

US3202042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:19:02
User entered '24 Sep 2020'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 17:21:27

US3202042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:19:02
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 17:21:27

US3202042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:19:02
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 17:21:27

US3202042

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:19:15
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 17:21:32

US3202042

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'I'	System	24 Sep 2020 17:21:32

US3202042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:19:33
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:53:39

US3202042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:19:33
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 14:03:05
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	zackery harmon (b) (4)	16 Oct 2020 20:54:37
answered with 'PD noted OOW' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Oct 2020 20:53:39
User entered '30 Sep 2020'	zackery harmon (b) (4)	16 Oct 2020 20:53:39
	(b) (4)	

US3202042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:19:33
User entered 'Contact Made (CONTACT MADE)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:53:39

US3202042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:19:33
User entered empty.	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:53:39

US3202042

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:49:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:19:42
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:54:42

US3202042

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'I'	System	16 Oct 2020 20:54:42

US3202042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:29
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:15

US3202042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:29
User entered '08 Oct 2020'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:15

US3202042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:29
User entered 'Clinic (Clinic)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:15

US3202042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'VISIT3'	System	16 Oct 2020 20:57:15

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:50
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:50
User entered '08 Oct 2020'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:50
User entered '14:33'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '08 Oct 2020 14:33'	System	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:50
User entered '36.8' C	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:50
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:50
User entered empty.	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:50
User entered '78'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'bpm'	System	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:50
User entered '16'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'breaths/min'	System	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:50
User entered '121'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'mmHg'	System	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:50
User entered '78'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'mmHg'	System	16 Oct 2020 20:57:37

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53

US3202042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53

US3202042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:59
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:41

US3202042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:23:59
User entered empty.	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:57:41

US3202042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:24:11
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 21:00:43

US3202042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:24:11
User entered '08 Oct 2020'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 21:00:43

US3202042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:24:11
User entered '14:40'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 21:00:43

US3202042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '08 Oct 2020 14:40'	System	16 Oct 2020 21:00:43

US3202042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:50:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:24:17
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 21:00:48

US3202042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered '1'	System	16 Oct 2020 21:00:48

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 64'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-10-09T10:53:05', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'ba31392c-9551-419d-a1db-3f0daf96812c'	System	09 Oct 2020 14:53:24
User entered 'No (N)'	System	09 Oct 2020 14:53:24

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-10-09T10:53:14', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'ba31392c-9551-419d-a1db-3f0daf96812c'	System	09 Oct 2020 14:53:24
User entered 'No (N)'	System	09 Oct 2020 14:53:24

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-10-09T10:53:20', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'ba31392c-9551-419d-a1db-3f0daf96812c'	System	09 Oct 2020 14:53:24
User entered '09 Oct 2020 10:53:20'	System	09 Oct 2020 14:53:24

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 71'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-10-15T12:07:52', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'aee9487b-50ef-49e8-bb88-4542f6a960de'	System	15 Oct 2020 16:08:05
User entered 'No (N)'	System	15 Oct 2020 16:08:05

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-10-15T12:07:55', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'aee9487b-50ef-49e8-bb88-4542f6a960de'	System	15 Oct 2020 16:08:05
User entered 'No (N)'	System	15 Oct 2020 16:08:05

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-10-15T12:08:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'aee9487b-50ef-49e8-bb88-4542f6a960de'	System	15 Oct 2020 16:08:05
User entered '15 Oct 2020 12:08:00'	System	15 Oct 2020 16:08:05

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 78'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-10-20T04:26:54', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '765dd9dd-d5a8-4857-b259-c36012a2d041'	System	20 Oct 2020 08:27:10
User entered 'No (N)'	System	20 Oct 2020 08:27:10

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-10-20T04:27:03', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '765dd9dd-d5a8-4857-b259-c36012a2d041'	System	20 Oct 2020 08:27:10
User entered 'No (N)'	System	20 Oct 2020 08:27:10

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-10-20T04:27:08', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '765dd9dd-d5a8-4857-b259-c36012a2d041'	System	20 Oct 2020 08:27:10
User entered '20 Oct 2020 04:27:08'	System	20 Oct 2020 08:27:10

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 92'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-11-05T14:41:58', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'c254951d-4664-4768-9abb-010c62b1188e'	System	05 Nov 2020 19:42:32
User entered 'No (N)'	System	05 Nov 2020 19:42:32

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Have you been exposed to someone with 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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-11-05T14:42:03', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'c254951d-4664-4768-9abb-010c62b1188e'	System	05 Nov 2020 19:42:32
User entered 'Yes (Y)'	System	05 Nov 2020 19:42:32

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-11-05T14:42:15', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'c254951d-4664-4768-9abb-010c62b1188e'	System	05 Nov 2020 19:42:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Nov 2020 19:42:32

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-11-05T14:42:23', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'c254951d-4664-4768-9abb-010c62b1188e' User entered '05 Nov 2020 14:42:23'	System	05 Nov 2020 19:42:32
	System	05 Nov 2020 19:42:32

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 99'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-11-10T09:44:31', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '1f73cfce-f457-4554-be11-cb175ec7cd34'	System	10 Nov 2020 14:45:38
User entered 'No (N)'	System	10 Nov 2020 14:45:38

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-11-10T09:45:02', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '1f73cfce-f457-4554-be11-cb175ec7cd34'	System	10 Nov 2020 14:45:38
User entered 'No (N)'	System	10 Nov 2020 14:45:38

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-11-10T09:45:35', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '1f73cfce-f457-4554-be11-cb175ec7cd34'	System	10 Nov 2020 14:45:38
User entered '10 Nov 2020 09:45:35'	System	10 Nov 2020 14:45:38

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered 'Day 106'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-11-17T03:51:53', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '7c6019a9-214d-4b2d-87bc-00118fa0055d'	System	17 Nov 2020 08:52:17
User entered 'No (N)'	System	17 Nov 2020 08:52:17

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-11-17T03:52:08', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '7c6019a9-214d-4b2d-87bc-00118fa0055d'	System	17 Nov 2020 08:52:17
User entered 'No (N)'	System	17 Nov 2020 08:52:17

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-11-17T03:52:13', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '7c6019a9-214d-4b2d-87bc-00118fa0055d' User entered '17 Nov 2020 03:52:13'	System	17 Nov 2020 08:52:17
	System	17 Nov 2020 08:52:17

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 20:23:30

US3202042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:07:15
Data entry locked.	System	06 Aug 2020 20:23:30
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 20:23:30

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2020-11-24T12:24:55', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b5f69020-ee19-4495-bd76-9449e7e64eef'	System	24 Nov 2020 17:25:18
User entered 'No (N)'	System	24 Nov 2020 17:25:18

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2020-11-24T12:25:03', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b5f69020-ee19-4495-bd76-9449e7e64eef'	System	24 Nov 2020 17:25:18
User entered 'No (N)'	System	24 Nov 2020 17:25:18

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-11-24T12:25:16', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'b5f69020-ee19-4495-bd76-9449e7e64eef'	System	24 Nov 2020 17:25:18
User entered '24 Nov 2020 12:25:16'	System	24 Nov 2020 17:25:18

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2020-11-28T07:20:05', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '1760d3d8-9a7f-4596-8806-48dfd73e6764'	System	28 Nov 2020 12:20:21
User entered 'No (N)'	System	28 Nov 2020 12:20:21

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2020-11-28T07:20:11', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '1760d3d8-9a7f-4596-8806-48dfd73e6764'	System	28 Nov 2020 12:20:21
User entered 'No (N)'	System	28 Nov 2020 12:20:21

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-11-28T07:20:16', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '1760d3d8-9a7f-4596-8806-48dfd73e6764'	System	28 Nov 2020 12:20:21
User entered '28 Nov 2020 07:20:16'	System	28 Nov 2020 12:20:21

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2020-12-05T11:18:23', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '6b59453a-2142-4c26-a318-2634f71a0586'	System	05 Dec 2020 16:18:40
User entered 'No (N)'	System	05 Dec 2020 16:18:40

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2020-12-05T11:18:31', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '6b59453a-2142-4c26-a318-2634f71a0586'	System	05 Dec 2020 16:18:40
User entered 'No (N)'	System	05 Dec 2020 16:18:40

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-12-05T11:18:36', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '6b59453a-2142-4c26-a318-2634f71a0586'	System	05 Dec 2020 16:18:40
User entered '05 Dec 2020 11:18:36'	System	05 Dec 2020 16:18:40

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2020-12-16T12:50:05', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5ae2ca91-2ac3-418f-8191-ee87864c235c'	System	16 Dec 2020 17:50:28
User entered 'No (N)'	System	16 Dec 2020 17:50:28

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2020-12-16T12:50:10', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5ae2ca91-2ac3-418f-8191-ee87864c235c'	System	16 Dec 2020 17:50:28
User entered 'Yes (Y)'	System	16 Dec 2020 17:50:28

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-12-16T12:50:14', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5ae2ca91-2ac3-418f-8191-ee87864c235c'	System	16 Dec 2020 17:50:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 17:50:28

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-12-16T12:50:17', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '5ae2ca91-2ac3-418f-8191-ee87864c235c'	System	16 Dec 2020 17:50:28
User entered '16 Dec 2020 12:50:17'	System	16 Dec 2020 17:50:28

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2020-12-19T13:04:47', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'da705b01-205a-4edc-b632-fcab428c8df9'	System	19 Dec 2020 18:05:04
User entered 'No (N)'	System	19 Dec 2020 18:05:04

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2020-12-19T13:04:57', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'da705b01-205a-4edc-b632-fcab428c8df9'	System	19 Dec 2020 18:05:04
User entered 'No (N)'	System	19 Dec 2020 18:05:04

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-12-19T13:04:59', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'da705b01-205a-4edc-b632-fcab428c8df9'	System	19 Dec 2020 18:05:04
User entered '19 Dec 2020 13:04:59'	System	19 Dec 2020 18:05:04

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2020-12-26T10:30:18', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0efd4993-f651-4b32-b039-53c3da9b8cb6'	System	26 Dec 2020 15:30:29
User entered 'No (N)'	System	26 Dec 2020 15:30:29

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2020-12-26T10:30:22', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0efd4993-f651-4b32-b039-53c3da9b8cb6'	System	26 Dec 2020 15:30:29
User entered 'No (N)'	System	26 Dec 2020 15:30:29

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2020-12-26T10:30:25', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '0efd4993-f651-4b32-b039-53c3da9b8cb6'	System	26 Dec 2020 15:30:29
User entered '26 Dec 2020 10:30:25'	System	26 Dec 2020 15:30:29

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-01-02T07:06:39', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd618dd9a-3a21-49af-88ba-93b72c7d8b74'	System	02 Jan 2021 12:06:50
User entered 'No (N)'	System	02 Jan 2021 12:06:50

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-01-02T07:06:44', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd618dd9a-3a21-49af-88ba-93b72c7d8b74'	System	02 Jan 2021 12:06:50
User entered 'No (N)'	System	02 Jan 2021 12:06:50

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-01-02T07:06:50', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd618dd9a-3a21-49af-88ba-93b72c7d8b74'	System	02 Jan 2021 12:06:50
User entered '02 Jan 2021 07:06:50'	System	02 Jan 2021 12:06:50

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-01-09T04:54:27', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bc0ae7d3-7e0a-4278-8e4c-5cfb9a50bc6f'	System	09 Jan 2021 09:56:17
User entered 'Yes (Y)'	System	09 Jan 2021 09:56:17

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-01-09T04:54:35', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bc0ae7d3-7e0a-4278-8e4c-5cfb9a50bc6f'	System	09 Jan 2021 09:56:17
User entered 'No (N)'	System	09 Jan 2021 09:56:17

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-01-09T04:54:45', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bc0ae7d3-7e0a-4278-8e4c-5cfb9a50bc6f'	System	09 Jan 2021 09:56:17
User entered 'No (N)'	System	09 Jan 2021 09:56:17

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-01-09T04:55:50', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bc0ae7d3-7e0a-4278-8e4c-5cfb9a50bc6f'	System	09 Jan 2021 09:56:17
User entered 'Yes (Y)'	System	09 Jan 2021 09:56:17

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-01-09T04:55:59', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bc0ae7d3-7e0a-4278-8e4c-5cfb9a50bc6f'	System	09 Jan 2021 09:56:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Jan 2021 09:56:17

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-01-09T04:56:08', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'bc0ae7d3-7e0a-4278-8e4c-5cfb9a50bc6f'	System	09 Jan 2021 09:56:17
User entered '09 Jan 2021 04:56:08'	System	09 Jan 2021 09:56:17

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-01-16T09:30:09', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '76cea33b-d618-42d2-8614-96528f3c91ef'	System	16 Jan 2021 14:30:22
User entered 'No (N)'	System	16 Jan 2021 14:30:22

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-01-16T09:30:16', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '76cea33b-d618-42d2-8614-96528f3c91ef'	System	16 Jan 2021 14:30:22
User entered 'No (N)'	System	16 Jan 2021 14:30:22

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-01-16T09:30:21', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '76cea33b-d618-42d2-8614-96528f3c91ef'	System	16 Jan 2021 14:30:22
User entered '16 Jan 2021 09:30:21'	System	16 Jan 2021 14:30:22

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-01-23T08:33:18', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '7c8e6490-6d6a-443c-9d40-8d2989412b97'	System	23 Jan 2021 13:34:53
User entered 'Yes (Y)'	System	23 Jan 2021 13:34:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-01-23T08:33:32', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '7c8e6490-6d6a-443c-9d40-8d2989412b97'	System	23 Jan 2021 13:34:53
User entered 'No (N)'	System	23 Jan 2021 13:34:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-01-23T08:33:48', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '7c8e6490-6d6a-443c-9d40-8d2989412b97'	System	23 Jan 2021 13:34:53
User entered 'No (N)'	System	23 Jan 2021 13:34:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-01-23T08:34:21', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '7c8e6490-6d6a-443c-9d40-8d2989412b97'	System	23 Jan 2021 13:34:53
User entered 'Yes (Y)'	System	23 Jan 2021 13:34:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-01-23T08:34:41', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '7c8e6490-6d6a-443c-9d40-8d2989412b97'	System	23 Jan 2021 13:34:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Jan 2021 13:34:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-01-23T08:34:46', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '7c8e6490-6d6a-443c-9d40-8d2989412b97'	System	23 Jan 2021 13:34:53
User entered '23 Jan 2021 08:34:46'	System	23 Jan 2021 13:34:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-02-09T15:17:27', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd04762e6-101b-4fc2-bc32-2356ae969714'	System	09 Feb 2021 20:17:42
User entered 'No (N)'	System	09 Feb 2021 20:17:42

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-02-09T15:17:31', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd04762e6-101b-4fc2-bc32-2356ae969714'	System	09 Feb 2021 20:17:42
User entered 'No (N)'	System	09 Feb 2021 20:17:42

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-02-09T15:17:39', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'd04762e6-101b-4fc2-bc32-2356ae969714'	System	09 Feb 2021 20:17:42
User entered '09 Feb 2021 15:17:39'	System	09 Feb 2021 20:17:42

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-02-13T07:51:24', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '6e84a38c-eb21-4279-9cb3-1da80b64aff0'	System	13 Feb 2021 12:51:44
User entered 'No (N)'	System	13 Feb 2021 12:51:44

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-02-13T07:51:30', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '6e84a38c-eb21-4279-9cb3-1da80b64aff0'	System	13 Feb 2021 12:51:44
User entered 'No (N)'	System	13 Feb 2021 12:51:44

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-02-13T07:51:42', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '6e84a38c-eb21-4279-9cb3-1da80b64aff0'	System	13 Feb 2021 12:51:44
User entered '13 Feb 2021 07:51:42'	System	13 Feb 2021 12:51:44

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-02-22T13:24:30', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'e117970a-a7da-4a96-a9ca-8ca61b7cb195'	System	22 Feb 2021 18:25:19
User entered 'No (N)'	System	22 Feb 2021 18:25:19

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-02-22T13:24:34', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'e117970a-a7da-4a96-a9ca-8ca61b7cb195'	System	22 Feb 2021 18:25:19
User entered 'No (N)'	System	22 Feb 2021 18:25:19

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-02-22T13:24:40', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'e117970a-a7da-4a96-a9ca-8ca61b7cb195'	System	22 Feb 2021 18:25:19
User entered '22 Feb 2021 13:24:40'	System	22 Feb 2021 18:25:19

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-02-27T06:22:16-05:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a8c827e4-9b32-49d7-b8d8-d419750f558e'	System	27 Feb 2021 11:22:24
User entered 'No (N)'	System	27 Feb 2021 11:22:24

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-02-27T06:22:20-05:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a8c827e4-9b32-49d7-b8d8-d419750f558e'	System	27 Feb 2021 11:22:24
User entered 'No (N)'	System	27 Feb 2021 11:22:24

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-02-27T06:22:23-05:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a8c827e4-9b32-49d7-b8d8-d419750f558e' User entered '27 Feb 2021 06:22:23'	System	27 Feb 2021 11:22:24
	System	27 Feb 2021 11:22:24

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-03-06T06:14:01-05:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '3f20cb5d-bac4-4e2c-a9d2-985f77a625d8'	System	06 Mar 2021 11:14:11
User entered 'No (N)'	System	06 Mar 2021 11:14:11

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-03-06T06:14:05-05:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '3f20cb5d-bac4-4e2c-a9d2-985f77a625d8'	System	06 Mar 2021 11:14:11
User entered 'No (N)'	System	06 Mar 2021 11:14:11

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-03-06T06:14:08-05:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '3f20cb5d-bac4-4e2c-a9d2-985f77a625d8'	System	06 Mar 2021 11:14:11
User entered '06 Mar 2021 06:14:08'	System	06 Mar 2021 11:14:11

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-03-14T07:52:07-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '600e1fcb-fb1d-44e3-87c4-6d92d802f44e'	System	14 Mar 2021 11:52:29
User entered 'No (N)'	System	14 Mar 2021 11:52:29

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-03-14T07:52:12-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '600e1fcb-fb1d-44e3-87c4-6d92d802f44e'	System	14 Mar 2021 11:52:29
User entered 'No (N)'	System	14 Mar 2021 11:52:29

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-03-14T07:52:27-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '600e1fcb-fb1d-44e3-87c4-6d92d802f44e' User entered '14 Mar 2021 07:52:27'	System	14 Mar 2021 11:52:29
	System	14 Mar 2021 11:52:29

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-03-20T07:20:06-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '99d509b6-d5e8-42d9-bbed-0d9ae5b25a0f' User entered 'No (N)'	System	20 Mar 2021 11:20:18
	System	20 Mar 2021 11:20:18

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-03-20T07:20:11-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '99d509b6-d5e8-42d9-bbed-0d9ae5b25a0f'	System	20 Mar 2021 11:20:18
User entered 'No (N)'	System	20 Mar 2021 11:20:18

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-03-20T07:20:15-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '99d509b6-d5e8-42d9-bbed-0d9ae5b25a0f' User entered '20 Mar 2021 07:20:15'	System	20 Mar 2021 11:20:18
	System	20 Mar 2021 11:20:18

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-03-27T18:18:19-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'f8e930aa-a523-4a1e-9e80-26ea6cf51589'	System	27 Mar 2021 22:18:33
User entered 'No (N)'	System	27 Mar 2021 22:18:33

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-03-27T18:18:24-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'f8e930aa-a523-4a1e-9e80-26ea6cf51589'	System	27 Mar 2021 22:18:33
User entered 'No (N)'	System	27 Mar 2021 22:18:33

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-03-27T18:18:28-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'f8e930aa-a523-4a1e-9e80-26ea6cf51589'	System	27 Mar 2021 22:18:33
User entered '27 Mar 2021 18:18:28'	System	27 Mar 2021 22:18:33

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-04-14T07:28:05-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'cbbdf6c9-7faf-4aac-9495-e040052777ac' User entered 'No (N)'	System	14 Apr 2021 12:47:22
	System	14 Apr 2021 12:47:22

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-04-14T07:28:25-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'cbbdf6c9-7faf-4aac-9495-e040052777ac'	System	14 Apr 2021 12:47:22
User entered 'No (N)'	System	14 Apr 2021 12:47:22

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-04-14T07:28:28-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'cbbdf6c9-7faf-4aac-9495-e040052777ac'	System	14 Apr 2021 12:47:22
User entered '14 Apr 2021 07:28:28'	System	14 Apr 2021 12:47:22

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-04-17T08:21:03-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a40adf5f-a69e-4749-a025-5aaa95723974'	System	17 Apr 2021 12:21:17
User entered 'No (N)'	System	17 Apr 2021 12:21:17

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-04-17T08:21:08-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a40adf5f-a69e-4749-a025-5aaa95723974'	System	17 Apr 2021 12:21:17
User entered 'No (N)'	System	17 Apr 2021 12:21:17

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-04-17T08:21:11-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a40adf5f-a69e-4749-a025-5aaa95723974'	System	17 Apr 2021 12:21:17
User entered '17 Apr 2021 08:21:11'	System	17 Apr 2021 12:21:17

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-04-24T06:23:41-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ea1330b-a245-438e-8b81-b65985d99b07'	System	24 Apr 2021 10:23:52
User entered 'No (N)'	System	24 Apr 2021 10:23:52

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-04-24T06:23:45-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ea1330b-a245-438e-8b81-b65985d99b07'	System	24 Apr 2021 10:23:52
User entered 'No (N)'	System	24 Apr 2021 10:23:52

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-04-24T06:23:50-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '2ea1330b-a245-438e-8b81-b65985d99b07'	System	24 Apr 2021 10:23:52
User entered '24 Apr 2021 06:23:50'	System	24 Apr 2021 10:23:52

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[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 (362d39b34428f1d2)', Time: '2021-05-02T20:41:31-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a9f39a0e-5558-40b6-83f1-21a582767206'	System	03 May 2021 00:41:44
User entered 'No (N)'	System	03 May 2021 00:41:44

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

Have you been exposed to someone with 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 (362d39b34428f1d2)', Time: '2021-05-02T20:41:35-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a9f39a0e-5558-40b6-83f1-21a582767206'	System	03 May 2021 00:41:44
User entered 'No (N)'	System	03 May 2021 00:41:44

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-05-02T20:41:38-04:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: 'a9f39a0e-5558-40b6-83f1-21a582767206'	System	03 May 2021 00:41:44
User entered '02 May 2021 20:41:38'	System	03 May 2021 00:41:44

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 15:04:53

US3202042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:04:53
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 15:04:53

US3202042

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:41:24

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:00:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-03-06T06:14:18-05:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '414719f2-31f0-47f0-bd1d-5296f4060cbb'	System	06 Mar 2021 11:14:33
User entered 'No (N)'	System	06 Mar 2021 11:14:33

US3202042

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:41:24

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:00:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (362d39b34428f1d2)', Time: '2021-03-06T06:14:30-05:00', User OID: 'PatientReportedOutcome (US3202042)', ODM File OID: '414719f2-31f0-47f0-bd1d-5296f4060cbb' User entered '06 Mar 2021 06:14:30'	System	06 Mar 2021 11:14:33
	System	06 Mar 2021 11:14:33

US3202042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:25:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:41:48
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 21:00:58

US3202042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:25:41
User entered '3 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:41:48
User entered empty.	zackery harmon (b) (4) (b) (4)	16 Oct 2020 21:00:58

US3202042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:25:41
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:41:48
User entered empty.	zackery harmon (b) (4) (b) (4)	16 Oct 2020 21:00:58

US3202042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:25:41
User entered empty.	zackery harmon (b) (4) (b) (4)	16 Oct 2020 21:00:58

US3202042

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:25:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 17:41:55

US3202042

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:53
User entered 'I'	System	03 Nov 2020 17:41:55

US3202042

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:31:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 16:16:45

US3202042

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:31:33
User entered '9 Dec 2020'	(b) (4), (b) (6)	09 Dec 2020 16:16:45

US3202042

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:31:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Dec 2020 16:16:45

US3202042

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:31:33
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 16:16:45

US3202042

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:31:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 16:16:48

US3202042

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User entered 'I'	System	09 Dec 2020 16:16:48

US3202042

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:25:06
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	10 Jan 2021 19:24:25

US3202042

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:32:24
User closed query 'source = 10Jan2021 and not completed. Please verify' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 14:32:11
Query 'source = 10Jan2021 and not completed. Please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	26 Mar 2021 16:54:23
User entered '10 Jan 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Mar 2021 16:54:00
User opened query 'source = 10Jan2021 and not completed. Please verify' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 19:22:28
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	13 Jan 2021 21:48:01
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'subject called back' (Site from System).	zackery harmon (b) (4)	13 Jan 2021 13:56:26
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	13 Jan 2021 13:56:19
User entered '13 Jan 2021' reason for change: Data Entry Error	zackery harmon (b) (4)	13 Jan 2021 13:56:19
User entered '10 Jan 2021'	zackery harmon (b) (4)	10 Jan 2021 19:24:25

US3202042

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:32:24
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Mar 2021 16:54:00
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	zackery harmon (b) (4)	13 Jan 2021 13:56:19
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) zackery harmon (b) (4)	10 Jan 2021 19:24:25

US3202042

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:32:24
User entered 'X 3 ATTEMPTS; left VM' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Mar 2021 16:54:19
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	26 Mar 2021 16:54:09
User entered 'X 3 attempts' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Mar 2021 16:54:09
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	26 Mar 2021 16:54:00
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	13 Jan 2021 13:56:19
User entered 'LVM, attempts x3'	zackery harmon (b) (4)	10 Jan 2021 19:24:25

US3202042

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:25:10
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	10 Jan 2021 19:24:29

US3202042

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User entered '1'	System	10 Jan 2021 19:24:29

US3202042

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:25:37
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	16 Feb 2021 21:06:05

US3202042

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:25:37
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 10:34:21
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'missed calls' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	16 Feb 2021 21:06:13
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Feb 2021 21:06:05
User entered '16 Feb 2021'	Lilian Nukuna (b) (4) (b) (4)	16 Feb 2021 21:06:05

US3202042

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:25:37
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	16 Feb 2021 21:06:05

US3202042

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:25:37
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	16 Feb 2021 21:06:05

US3202042

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:25:50
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	16 Feb 2021 21:06:23

US3202042

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:19
User entered 'I'	System	16 Feb 2021 21:06:23

US3202042

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:34:38
User entered 'Yes (Y)'	Teresa Deese (b) (4)	03 Mar 2021 14:16:58

US3202042

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:34:38
User entered '3 Mar 2021'	Teresa Deese (b) (4)	03 Mar 2021 14:16:58

US3202042

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[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 06:05:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:34:38
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	03 Mar 2021 14:16:58

US3202042

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User entered 'VISIT4'	System	03 Mar 2021 14:16:58

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User entered empty.	System	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User entered empty.	System	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User entered empty.	System	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User entered empty.	System	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User entered empty.	System	30 Mar 2021 18:48:25

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33

US3202042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33

US3202042

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:34:45
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:17:04

US3202042

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:34:45
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:17:04

US3202042

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:34:52
User entered 'Yes (Y)'	Teresa Deese (b) (4)	03 Mar 2021 14:17:17

US3202042

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:34:52
User entered '3 Mar 2021'	Teresa Deese (b) (4)	03 Mar 2021 14:17:17

US3202042

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:34:52
User entered '08:33'	Teresa Deese (b) (4)	03 Mar 2021 14:17:17

US3202042

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User entered '3 Mar 2021 08:33'	System	03 Mar 2021 14:17:17

US3202042

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:34:57
User entered 'Yes (Y)'	Teresa Deese (b) (4)	03 Mar 2021 14:19:31

US3202042

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:05:33
User entered 'I'	System	03 Mar 2021 14:19:31

US3202042

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

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:33:36
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:19:41

US3202042

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

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:33:36
User entered '04 Jan 2021'	Erica Osmundsen (b) (4)	11 Jan 2021 21:19:41

US3202042

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

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:33:36
User entered 'Clinic (Clinic)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:19:41

US3202042

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

Form: Visit Date

Generated On: 09 Jun 2021 15:41:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 21:19:41

US3202042

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:24

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:34:39
User entered '04 Jan 2021'	Erica Osmundsen (b) (4)	11 Jan 2021 21:20:25

US3202042

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:24

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:52:53
User entered '0'	(b) (4) Teresa Deese (b) (4)	22 Apr 2021 14:56:34
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:22:43

US3202042

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:24

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:34:39
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:20:25

US3202042

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:24

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:00
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) (6)	22 Apr 2021 18:32:10
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:52:53
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 'done' (Site from DM).	Teresa Deese (b) (4)	22 Apr 2021 14:57:06
User entered 'Amendment 6 or later (Amendment 6 or later)'	Teresa Deese (b) (4)	22 Apr 2021 14:56:34
User opened query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:19:48
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:22:43

US3202042

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:24

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:34:39
User entered '04 Jan 2021'	Erica Osmundsen (b) (4)	11 Jan 2021 21:20:25

US3202042

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:34:39
User entered 'mRNA-1273 (mRNA-1273)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:20:25

US3202042

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:24

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:25:36
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:34:39
User entered 'mRNA-1273 (mRNA-1273)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:20:25

US3202042

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:24

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:25:36
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:34:39
User entered 'mRNA-1273 (mRNA-1273)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:20:25

US3202042

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:24

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:34:39
User entered 'No (N)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:20:25

US3202042

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:24

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User entered empty.	System	11 Jan 2021 21:20:25

US3202042

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

Form: Unblinding

Generated On: 09 Jun 2021 15:41:24

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User entered empty.	System	11 Jan 2021 21:20:25

US3202042

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:34:49
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:21:50

US3202042

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:34:49
User entered '04 Jan 2021'	Erica Osmundsen (b) (4)	11 Jan 2021 21:21:50

US3202042

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:34:49
User entered '15:18'	Erica Osmundsen (b) (4)	11 Jan 2021 21:21:50

US3202042

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User entered '04 Jan 2021 15:18'	System	11 Jan 2021 21:21:50

US3202042

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:34:56
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:21:59

US3202042

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:34:56
User entered '04 Jan 2021'	Erica Osmundsen (b) (4)	11 Jan 2021 21:21:59

US3202042

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:24

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:34:56
User entered '15:15'	Erica Osmundsen (b) (4)	11 Jan 2021 21:21:59

US3202042

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:24

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:10
User entered '04 Jan 2021 15:15'	System	11 Jan 2021 21:21:59

US3202042

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:41:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:13
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:01:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:19:18
DataPoint Un-verified.	Erica Osmundsen (b) (4)	11 Jan 2021 21:27:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	11 Jan 2021 21:27:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:37:05
User entered 'No (N)'	zackery harmon (b) (4)	03 Oct 2020 14:30:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User closed query 'For coding purposes, for term BLOOD CLOT IN NECK, is this a Carotid artery thrombosis, Juglular Vein thrombosis or something else. Please update the term with your response.' (Site from Coder).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:58:11
Query 'For coding purposes, for term BLOOD CLOT IN NECK, is this a Carotid artery thrombosis, Juglular Vein thrombosis or something else. Please update the term with your response.' answered with 'TERM UPDATED NOW THAT MEDICAL RECORDS RECEIVED' (Site from Coder).	Erica Osmundsen (b) (4)	29 Jan 2021 21:14:07
User opened query 'For coding purposes, for term BLOOD CLOT IN NECK, is this a Carotid artery thrombosis, Juglular Vein thrombosis or something else. Please update the term with your response.' (Site from Coder).	(b) (4), (b) (6)	26 Jan 2021 12:00:17
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:37:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:56:44
User entered 'USA-US128-2021-mRNA-1273-P301000005'	System	12 Jan 2021 18:56:39
User entered 'New'	(b) (4), (b) (6)	12 Jan 2021 18:56:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Jugular vein thrombosis, LLT: Jugular vein thrombosis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	02 Mar 2021 08:24:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:24:11
User closed query 'For coding purposes, please split DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR AND SUBCLAVIAN VEINS into separate entries. 1. DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR and 2. DEEP VEIN THROMBOSIS SUBCLAVIAN VEINS' (Site from Coder).	(b) (4), (b) (6)	28 Feb 2021 13:29:58
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 16:13:47
User closed query 'Per source D/C diagnosis = Partially Occlusive Left Internal Jugular Vein DVT and Occlusive Left Subclavian Vein DVT, Please verify' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 16:13:06
Data point term sent to Coder	System	10 Feb 2021 16:01:30
Query 'Per source D/C diagnosis = Partially Occlusive Left Internal Jugular Vein DVT and Occlusive Left Subclavian Vein DVT, Please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	10 Feb 2021 16:01:02
Query 'For coding purposes, please split DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR AND SUBCLAVIAN VEINS into separate entries. 1. DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR and 2. DEEP VEIN THROMBOSIS SUBCLAVIAN VEINS' answered with 'done' (Site from Coder).	Teresa Deese (b) (4)	10 Feb 2021 16:00:58
Coding entries removed.	Teresa Deese (b) (4)	10 Feb 2021 16:00:33
User entered 'DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR - partially occlusive' reason for change: Data Entry Error	Teresa Deese (b) (4)	10 Feb 2021 16:00:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per source D/C diagnosis = Partially Occlusive Left Internal Jugular Vein DVT and Occlusive Left Subclavian Vein DVT, Please verify' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 14:42:27
User closed query 'term does not match AE log, please verify' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 14:59:21
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 14:00:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 14:00:28
User opened query 'For coding purposes, please split DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR AND SUBCLAVIAN VEINS into separate entries. 1. DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR and 2. DEEP VEIN THROMBOSIS SUBCLAVIAN VEINS' (Site from Coder).	(b) (4), (b) (6)	02 Feb 2021 13:59:46
User closed query 'Per DM CLR: Please review and update AE term to reflect specific body location of BLOOD CLOT. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 10:27:53
Query 'Per DM CLR: Please review and update AE term to reflect specific body location of BLOOD CLOT. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'UPDATED PER MEDICAL RECORDS' (Site from DM).	Erica Osmundsen (b) (4)	29 Jan 2021 21:14:15
Data point term sent to Coder	System	29 Jan 2021 21:13:05
Coding entries removed.	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
User entered 'DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR AND SUBCLAVIAN VEINS' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Clot blood - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 13:46:29

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System zackery harmon (b) (4) (b) (4)	28 Jan 2021 13:46:29 28 Jan 2021 13:45:54 28 Jan 2021 13:45:42
User entered 'BLOOD CLOT' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	28 Jan 2021 13:45:42
Query 'term does not match AE log, please verify' answered with 'updated to match ae log, requested records to update with proper diagnosis and location of the clot' (Site from CRA).	zackery harmon (b) (4) (b) (4)	28 Jan 2021 13:45:26
User opened query 'term does not match AE log, please verify' (Site from CRA).	(b) (4), (b) (6) (b) (4)	27 Jan 2021 17:11:56
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Clot blood - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 12:01:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder DataPoint Un-verified.	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6) (b) (4)	26 Jan 2021 12:01:39 24 Jan 2021 17:00:11 24 Jan 2021 16:59:23
Coding entries removed.	(b) (4), (b) (6) (b) (4)	24 Jan 2021 16:59:23
User entered 'BLOOD CLOT IN NECK' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4)	24 Jan 2021 16:59:23
User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location of BLOOD CLOT. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	24 Jan 2021 07:11:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	13 Jan 2021 20:37:20
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Clot blood - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:48:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	11 Jan 2021 21:48:59 11 Jan 2021 21:32:37
User entered 'blood clot'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	11 Jan 2021 21:32:19

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered 'No (N)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered 'No (N)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (swelling on 06 Jan 2021 per discharge summary). If not updating the start date, please clarify. ' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:51:42
	(b) (4), (b) (6)	10 Feb 2021 16:13:09
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (swelling on 06 Jan 2021 per discharge summary). If not updating the start date, please clarify. ' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	10 Feb 2021 16:01:06
User entered '06 Jan 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	10 Feb 2021 16:00:53
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 14:44:00
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 14:43:56
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (swelling on 06 Jan 2021 per discharge summary). If not updating the start date, please clarify. ' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 17:51:44
	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
User entered '07 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered '06 Jan 2021'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered empty.	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:13:18
DataPoint Un-verified.	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:13:16
DataPoint Un-verified.	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
User entered '11 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered empty.	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered empty.	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 13:21:36
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:14:59
User entered empty.	System	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered 'Yes (Y)'	Erica Osmundsen (b) (4) 	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered '0'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered '0'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 13:21:58
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'EMAILED JUST NOW' (Site from Safety).	Erica Osmundsen (b) (4)	29 Jan 2021 21:22:57
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:15:55
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:37:20
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 13:13:26
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'discharge date unknown at this time' (Site from System).	Erica Osmundsen (b) (4)	11 Jan 2021 21:42:06
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	11 Jan 2021 21:32:19
User entered 'I'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:13:24
DataPoint Un-verified.	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
User entered '07 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered '06 Jan 2021'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 16:13:26
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 13:21:56
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'EMAILING NOW' (Site from Safety).	Erica Osmundsen (b) (4)	29 Jan 2021 21:16:44
DataPoint Un-verified.	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
User entered '11 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:14:44
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered empty.	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered 'No (N)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered empty.	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered '0'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered '0'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered '0'	Erica Osmundsen (b) (4) 	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4) 	11 Jan 2021 21:32:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4) 	11 Jan 2021 21:32:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Jan 2021 22:01:08
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Jan 2021 22:00:54
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered '0'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:13:31
User closed query 'Per CDM: Response noted. Please update once data becomes known. Thanks' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 10:26:51
User entered '1' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 22:01:08
Query 'Per CDM: Response noted. Please update once data becomes known. Thanks' answered by data change (Site from DM).	System	29 Jan 2021 22:00:54
DataPoint Un-verified.	Erica Osmundsen (b) (4)	29 Jan 2021 22:00:54
User entered '0' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 22:00:54
User opened query 'Per CDM: Response noted. Please update once data becomes known. Thanks' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:47:40
User closed query 'Per CDM: Other action taken is Concomitant Medication however, there is no corresponding Concomitant Medication record(s) for 'BLOOD CLOT'. Please review and reconcile accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:47:40
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:37:20
Query 'Per CDM: Other action taken is Concomitant Medication however, there is no corresponding Concomitant Medication record(s) for 'BLOOD CLOT'. Please review and reconcile accordingly.' answered with 'RECORDS REQUESTED, NOT YET RECEIVED' (Site from DM).	Erica Osmundsen (b) (4)	13 Jan 2021 13:22:46
User opened query 'Per CDM: Other action taken is Concomitant Medication however, there is no corresponding Concomitant Medication record(s) for 'BLOOD CLOT'. Please review and reconcile accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:44:41
User entered '1'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered '0'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 16:13:36
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 13:21:52
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'UPDATED' (Site from Safety).	Erica Osmundsen (b) (4)	29 Jan 2021 21:23:05
DataPoint Un-verified.	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:15:12
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered empty.	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:13:39
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 13:21:50
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)	01 Feb 2021 13:21:48
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)	01 Feb 2021 13:21:47
User closed query 'PV Query: Please clarify whether subject has any risk factors for blood clot (i.e. previous history of blood clot, family history, prolonged immobilization, smoking history).' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 13:21:45
User closed query 'Per DM CLR: SAE Narrative = SUBJECT HAD COSMETIC SURGERY ON ARMS ON 05JAN21. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 10:16:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = SUBJECT HAD COSMETIC SURGERY ON ARMS ON 05JAN21. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'ADDING NOW AS RECORDS JUST RECEIVED' (Site from DM).	Erica Osmundsen (b) (4)	29 Jan 2021 21:24:29
Query 'PV Query: Please clarify whether subject has any risk factors for blood clot (i.e. previous history of blood clot, family history, prolonged immobilization, smoking history). ' answered with 'NO KNOWN RISK FACTORS OTHER THAN RECENT SURGERY' (Site from Safety).	Erica Osmundsen (b) (4)	29 Jan 2021 21:23:59
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'NO COVID-19 TESTING NOTED IN RECORDS' (Site from Safety).	Erica Osmundsen (b) (4)	29 Jan 2021 21:23:42
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 'D/C SUMMARY EMAILED TODAY' (Site from Safety).	Erica Osmundsen (b) (4)	29 Jan 2021 21:23:32
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'ENTERING CONMEDS FROM MEDICAL RECORDS NOW' (Site from Safety).	Erica Osmundsen (b) (4)	29 Jan 2021 21:23:19
DataPoint Un-verified.	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'UPDATE29/JAN/2021--MEDICAL RECORDS RECEIVED YESTERDAY AFTERNOON AND REVIEWED BY SUB-I AND SC, RESULTING IN UPDATED INFORMATION REGARDING AE TERM, HOSPITALIZATION DATES, ETC. SUBJECT HAD OUTPATIENT COSMETIC SURGERY (BILATERAL BRACHIOPLASTY AND BILATERAL THIGH LIFT) ON 05JAN2021. SHE REPORTED TO ER ON 07/JAN/2021 FOR SWELLING AND PAIN. SHE WAS FOUND TO HAVE DVTS, HOSPITALIZED THROUGH 11/JAN/2021 D/C ON XARELTO.. SITE NOTIFIED ON 11/JAN/21 THAT SUBJECT HAD COSMETIC SURGERY ON ARMS ON 05JAN21 AND DEVELOPED A BLOOD CLOT IN HER NECK SO SHE WAS KEPT AT HOSPITAL. DETAILS PROVIDED BY FRIEND VIA PHONE. RECORDS REQUESTED AND WILL UPDATE WHEN MORE INFORMATION COLLECTED.' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 21:12:29
User opened query 'Per DM CLR: SAE Narrative = SUBJECT HAD COSMETIC SURGERY ON ARMS ON 05JAN21. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 07:11:21
User opened query 'PV Query: Please clarify whether subject has any risk factors for blood clot (i.e. previous history of blood clot, family history, prolonged immobilization, smoking history).' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:16:44
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:16:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:15:34
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:15:23
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:37:20
User entered 'site notified on 11/JAN/21 that subject had cosmetic surgery on arms on 05JAN21 and developed a blood clot in her neck so she was kept at hospital. Details provided by friend via phone. records requested and will update when more information collected'	Erica Osmundsen (b) (4)	11 Jan 2021 21:32:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 21:32:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Jan 2021 21:32:19

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:09:49
User coded data point as SOC: Vascular disorders, HLT: Vascular haemorrhagic disorders, HLT: Haemorrhages NEC, PT: Haematoma, LLT: Groin hematoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Feb 2021 14:04:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Feb 2021 14:04:30
Data point term sent to Coder	System	29 Jan 2021 21:49:38
User entered 'RIGHT GROIN HEMATOMA'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:09:50
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:09:52
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:09:54
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:09:56
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:09:58
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User entered empty.	System	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:00
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:02
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:05
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User entered empty.	System	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:25
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:34
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:37
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:45
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:46
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:49
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:50
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:52
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:56
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:11:00
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:10:58
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:11:01
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:11:04
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:11:05
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:11:07
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:11:09
User entered 'I'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:11:12
User entered 'I'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:11:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:11:15
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:11:17
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User entered '0'	System	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45
User entered 'I'	System	29 Jan 2021 21:49:01

US3202042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:33
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:17
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:28:45

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:55
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Unilateral leg swelling - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 00:23:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 00:23:48
Data point term sent to Coder	System	29 Jan 2021 21:50:40
User entered 'RIGHT LEG PAINFUL SWELLING'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:54
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:52
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:50
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:49
User entered '19 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:47
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User entered empty.	System	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:45
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:44
User entered '22 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:41
User entered '19 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:42
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User entered empty.	System	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:38
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:35
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:34
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:32
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:29
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:27
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:24
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:23
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:21
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:19
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:17
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:15
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:14
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:12
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:10
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:08
User entered 'I'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:06
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:03
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:12:01
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User entered '0'	System	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00
User entered 'l'	System	29 Jan 2021 21:50:18

US3202042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:20:35
Data hard unlocked.	(b) (4), (b) (6)	05 Apr 2021 01:32:22
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:29:00

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:40:04
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:10:34
User entered 'USA-US128-2021-mRNA-1273-P301000005'	(b) (4), (b) (6)	11 Feb 2021 17:10:26

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Subclavian vein thrombosis, LLT: Subclavian vein thrombosis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 21:50:01
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 21:50:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 16:15:58
Data point term sent to Coder	System	10 Feb 2021 16:03:34
User entered 'DVT- occlusive left subclavian vein'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered 'Yes (Y)'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered 'No (N)'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered 'No (N)'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered '6 Jan 2021'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered 'No (N)'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered '11 Jan 2021'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 17:45:12
User closed query 'source = 3, please verify' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 17:45:11
Query 'source = 3, please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	10 Feb 2021 19:25:53
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Teresa Deese (b) (4)	10 Feb 2021 19:25:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 16:16:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 16:15:58
User opened query 'source = 3, please verify' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 16:14:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:12
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Feb 2021 16:04:20
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Feb 2021 16:03:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:16
User entered '0'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:18
User entered '0'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 16:15:20
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'done' (Site from System).	Teresa Deese (b) (4)	10 Feb 2021 16:04:28
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		10 Feb 2021 16:04:20
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		10 Feb 2021 16:04:20
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	10 Feb 2021 16:04:20
User entered '1' reason for change: Data Entry Error	Teresa Deese (b) (4)	10 Feb 2021 16:04:20
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	10 Feb 2021 16:04:00
User entered '0'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:24
User entered '7 Jan 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	10 Feb 2021 16:04:00
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:27
User entered '11 Jan 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	10 Feb 2021 16:04:00
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered '0'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered '0'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:58
User entered '0'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:34
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:36
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:38
User entered 'Not Applicable (NOT APPLICABLE)'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:42
User entered '0'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:44
User entered 'I'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:46
User entered '0'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:50
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:52
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Feb 2021 16:04:00
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Feb 2021 16:04:00
User entered 'see narrative for IJ DVT' reason for change: Data Entry Error	Teresa Deese (b) (4) [REDACTED]	10 Feb 2021 16:04:00
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Feb 2021 16:03:02
User entered empty.	Teresa Deese (b) (4) [REDACTED]	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 16:03:02

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:28
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User coded data point as SOC: Vascular disorders, HLT: Vascular infections and inflammations, HLT: Phlebitis NEC, PT: Phlebitis, LLT: Phlebitis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 14:08:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 14:08:59
Data point term sent to Coder	System	03 Mar 2021 14:07:47
User entered 'phlebitis'	Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:29
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:33
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:36
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered '15 Feb 2021'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:37
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
User entered empty.	System	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:12:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	26 Mar 2021 16:52:57
	Teresa Deese (b) (4)	26 Mar 2021 16:52:57
Signature has been broken.	Teresa Deese (b) (4)	26 Mar 2021 16:52:57
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Mar 2021 16:52:57
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	26 Mar 2021 16:52:35
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:12:49
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	26 Mar 2021 16:52:35
DataPoint Un-verified.	Teresa Deese (b) (4)	26 Mar 2021 16:52:35
Signature has been broken.	Teresa Deese (b) (4)	26 Mar 2021 16:52:35
User entered '16 Mar 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Mar 2021 16:52:35
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	26 Mar 2021 16:52:10
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:41
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:43
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
User entered empty.	System	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:44
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:49
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered '0'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:51
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered '0'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered '0'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:54
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:56
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:38:59
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:39:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:39:02
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered '0'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:39:04
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered '0'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:39:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered '0'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:39:08
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:39:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:39:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:39:15
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered '0'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:39:17
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered 'l'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:39:20
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered '0'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:12:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User closed query 'source= 3. Not recovered/not resolved. Please verify' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:31:03
Query 'source= 3. Not recovered/not resolved. Please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	26 Mar 2021 16:53:10
Signature has been broken.	Teresa Deese (b) (4)	26 Mar 2021 16:52:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Mar 2021 16:52:10
User opened query 'source= 3. Not recovered/not resolved. Please verify' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 19:38:14
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:39:22
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered empty.	(b) (4)	03 Mar 2021 14:07:37
	Teresa Deese (b) (4)	

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:39:24
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:51
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
User entered '0'	System	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56
User entered 'I'	System	03 Mar 2021 14:07:37

US3202042

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:57:56

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User closed query 'Also Fentanyl 50 mcg IV on 19Jan2021, please verify' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:09:27
User closed query 'hospital records = Zofran, 4mg IV, at MAAE 19Jan2021, Please verify' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 16:09:23
Query 'Also Fentanyl 50 mcg IV on 19Jan2021, please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	10 Feb 2021 19:26:22
Query 'hospital records = Zofran, 4mg IV, at MAAE 19Jan2021, Please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	10 Feb 2021 19:26:18
User opened query 'Also Fentanyl 50 mcg IV on 19Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:14:29
User opened query 'hospital records = Zofran, 4mg IV, at MAAE 19Jan2021, Please verify' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:11:47
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 15:41:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:22:35

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Apr 2021 15:37:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 15:37:42
Data point term sent to Coder	System	07 Apr 2021 15:36:53
Coding entries removed.	Erica Osmundsen (b) (4)	07 Apr 2021 15:36:43
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 15:44:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 18:25:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 18:25:14
Data point term sent to Coder	System	11 Aug 2020 18:24:14
User entered 'Trazadone'	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:14:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User closed query 'Per CDM: Please consider to update the indication to reflect the underlying medical condition that TRAZADONE is being used to prevent/treat (e.g. INSOMNIA). Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:09:39
Query 'Per CDM: Please consider to update the indication to reflect the underlying medical condition that TRAZADONE is being used to prevent/treat (e.g. INSOMNIA). Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'corrected' (Site from DM).	Erica Osmundsen (b) (4)	07 Apr 2021 15:36:48
DataPoint Un-verified.	Erica Osmundsen (b) (4)	07 Apr 2021 15:36:43
User entered 'insomnia' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	07 Apr 2021 15:36:43
User opened query 'Per CDM: Please consider to update the indication to reflect the underlying medical condition that TRAZADONE is being used to prevent/treat (e.g. INSOMNIA). Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:22:09
User closed query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 22:51:15
Query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	zackery harmon (b) (4)	22 Sep 2020 16:10:21
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 15:44:31

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 09:56:34
User entered 'Sleep'	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered '150'	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:20:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 18:24:04
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 18:23:42
User entered 'UN UNK 2017'	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 18:23:42

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE, PRODUCTSYNONYM: TOPAMAX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 15:45:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 15:45:43
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	16 Sep 2020 15:44:31 16 Sep 2020 15:44:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE, PRODUCTSYNONYM: TOPAMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 21:07:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 21:07:17
Data point term sent to Coder User entered 'Topamax'	System (b) (4), (b) (6)	11 Aug 2020 18:25:19 11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'Back Pain'	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered '100'	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'three times daily (TID)'	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:20:21
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 18:24:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 18:24:47
User entered 'UN UNK 2019'	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:44:31
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 18:24:47

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 14:56:43
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 14:56:06
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:14:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN PORCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Jan 2021 00:04:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Jan 2021 00:04:26
	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 21:36:28
User entered 'HEPARIN (PORCINE 5,000 units/mL)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR AND SUBCLAVIAN VEINS'	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '5000'	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'IU (IU)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'once daily (QD)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 21:42:45
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '07 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '08 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	29 Jan 2021 21:42:45
User entered '07 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 21:42:45
User entered empty.	System	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 21:42:45
User entered empty.	System	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jan 2021 21:42:45
User entered empty.	System	29 Jan 2021 21:36:10

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 23:15:44
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 23:15:44
Data point term sent to Coder	System	03 Mar 2021 14:09:48
DataPoint Un-verified.	Teresa Deese (b) (4)	03 Mar 2021 14:08:53
Coding entries removed.	Teresa Deese (b) (4)	03 Mar 2021 14:08:53
User entered 'XARELTO (dosage changed)' reason for change: Data Entry Error	Teresa Deese (b) (4)	03 Mar 2021 14:08:53
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:14:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:48:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:48:23
Data point term sent to Coder	System	29 Jan 2021 21:47:36
User entered 'XARELTO'	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

PRODUCTION RELEASE (v12.003
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US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR AND SUBCLAVIAN VEINS'	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '10'	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '07 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:41:39
DataPoint Un-verified.	Teresa Deese (b) (4)	03 Mar 2021 14:08:41
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	03 Mar 2021 14:08:41
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) (6)	02 Mar 2021 17:37:45
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 'subject still taking medication per doctors orders' (Site from DM).	zackery harmon (b) (4) (b) (4)	01 Mar 2021 21:07:40
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)	01 Mar 2021 11:57:30
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:08:24
User closed query 'source = 14Feb2021, please verify' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 15:08:05
Query 'source = 14Feb2021, please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	26 Mar 2021 16:55:07
User entered '14 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Mar 2021 16:55:02
User opened query 'source = 14Feb2021, please verify' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 19:41:54
User closed query 'Per DM CLR: The corresponding AE has resolved on 11 JAN 2021, however the medication end date was 15 FEB 2021. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.'	(b) (4), (b) (6)	20 Mar 2021 15:33:12
(Site from DM).		
Query 'Per DM CLR: The corresponding AE has resolved on 11 JAN 2021, however the medication end date was 15 FEB 2021. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.'	zackery harmon (b) (4)	18 Mar 2021 11:07:56
' answered with 'even though it had resolved their physician wanted them to remain on the medication for additional time' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: The corresponding AE has resolved on 11 JAN 2021, however the medication end date was 15 FEB 2021. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.'	(b) (4), (b) (6)	18 Mar 2021 11:02:47
(Site from DM).		
DataPoint Un-verified.	Teresa Deese (b) (4)	03 Mar 2021 14:08:41
User entered '15 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	03 Mar 2021 14:08:41

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jan 2021 21:46:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 23:49:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 23:49:27
Data point term sent to Coder	System	29 Jan 2021 21:45:35
User entered 'heparin'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR AND SUBCLAVIAN VEINS'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '50'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'IU (IU)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'other (OTHER)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'VARIABLE DRIP'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '07 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '09 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User entered empty.	System	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User entered empty.	System	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:15
User entered empty.	System	29 Jan 2021 21:44:57

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jan 2021 00:15:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jan 2021 00:15:27
Data point term sent to Coder	System	29 Jan 2021 21:51:41
User entered 'MORPHINE'	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'RIGHT LEG HEMATOMA'	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '4'	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User entered empty.	System	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User entered empty.	System	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:20
User entered empty.	System	29 Jan 2021 21:51:13

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:11:07
Query 'hospital records also = Zofran, 4 mg IV, for MAAE on 19Jan2021. Please verify' canceled (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:11:05
User opened query 'hospital records also = Zofran, 4 mg IV, for MAAE on 19Jan2021. Please verify' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:10:41
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 15:10:03
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:14:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jan 2021 12:02:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jan 2021 12:02:19
Data point term sent to Coder	System	29 Jan 2021 21:52:42
User entered 'ZOFRAN'	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'RIGHT LEG HEMATOMA'	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '4'	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User entered empty.	System	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User entered empty.	System	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:25
User entered empty.	System	29 Jan 2021 21:52:04

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:50:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:50:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:14:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 00:15:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 00:15:34
Data point term sent to Coder	System	29 Jan 2021 21:54:43
User entered 'NORMAL SALINE FLUIDS'	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'RIGHT GROIN HEMATOMA'	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '1000'	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User entered empty.	System	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User entered empty.	System	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:32
User entered empty.	System	29 Jan 2021 21:54:07

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 23:49:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 23:49:26
Data point term sent to Coder	System	29 Jan 2021 21:55:44
User entered 'GENERAL ANESTHESIA'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'RIGHT GROIN HEMATOMA'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'UNK'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'UNKNOWN'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User entered empty.	System	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User entered empty.	System	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:37
User entered empty.	System	29 Jan 2021 21:55:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 15:41:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 15:41:28
Data point term sent to Coder	System	29 Jan 2021 21:57:47
User entered 'TRAMADOL'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'RIGHT LEG PAINFUL SWELLING'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '50'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '19 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '0'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered '22 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:14:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User entered empty.	System	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User entered empty.	System	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:43
User entered empty.	System	29 Jan 2021 21:57:18

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 10:21:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 10:21:02
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 16:17:54
Data point term sent to Coder	System	10 Feb 2021 16:08:45
User entered 'fentanyl'	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:17:56
User entered 'No (N)'	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:17:57
User entered 'right leg painful swelling'	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:01
User entered '50'	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:02
User entered 'ug (ug)'	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:04
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:06
User entered 'once (ONCE)'	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:08
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:11
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:13
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:15
User entered '19 Jan 2021'	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:19
User entered '0'	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:17
User entered 'No (N)'	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:22
User entered '19 Jan 2021'	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:24
User entered 'No (N)'	Teresa Deese (b) (4)	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User entered empty.	System	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User entered empty.	System	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:52
User entered empty.	System	10 Feb 2021 16:08:15

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 12:04:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 12:04:39
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 16:18:32
Data point term sent to Coder	System	10 Feb 2021 16:09:49
User entered 'zofran'	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:34
User entered 'No (N)'	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 08:30:48
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'per (b) (6) monitor instructions' (Site from DM).	zackery harmon (b) (4) (b) (4)	01 Mar 2021 21:09:41
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:45:51
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 16:18:36
User entered 'painful leg swelling'	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:38
User entered '4'	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:41
User entered 'mg (mg)'	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:43
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:45
User entered 'once (ONCE)'	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:47
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:50
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:53
User entered empty.	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:55
User entered '19 Jan 2021'	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:18:57
User entered '0'	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:19:00
User entered 'No (N)'	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:19:03
User entered '19 Jan 2021'	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:19:07
User entered 'No (N)'	Teresa Deese (b) (4)	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User entered empty.	System	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User entered empty.	System	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:55
User entered empty.	System	10 Feb 2021 16:09:25

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:12:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:12:05
Data point term sent to Coder	System	03 Mar 2021 14:10:49
User entered 'Xarelto'	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:06
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:08
User entered 'phlebitis in both legs'	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:10
User entered '20'	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:12
User entered 'mg (mg)'	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:14
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:16
User entered 'once daily (QD)'	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:19
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:20
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:22
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:24
User entered '15 Feb 2021'	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:26
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
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)	07 Apr 2021 15:22:38
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 'no stop date' (Site from DM).	Teresa Deese (b) (4)	06 Apr 2021 14:29:59
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)	03 Apr 2021 04:42:28
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:43:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:30
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:32
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Mar 2021 14:10:19

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:41:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:23:18
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:57:27

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:41:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:30:39
User entered '12 Jan 2021'	Erica Osmundsen (b) (4) 	29 Jan 2021 21:59:04

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:41:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:30:41
User entered 'INCISION AND DRAINAGE OF RIGHT GROIN HEMATOMA'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	29 Jan 2021 21:59:04

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:30:46
User entered 'Adverse Event (AE)'	Erica Osmundsen (b) (4) 	29 Jan 2021 21:59:04

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:41:24

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:30:49
User entered empty.	Erica Osmundsen (b) (4)	29 Jan 2021 21:59:04

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:41:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:23:34
User entered '05 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 21:59:47

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:41:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:23:39
User entered 'BILATERAL BRACHIOPLASTY'	Erica Osmundsen (b) (4)	29 Jan 2021 21:59:47

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:23:37
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	29 Jan 2021 21:59:47

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:41:24

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:23:41
User entered 'COSMETIC'	Erica Osmundsen (b) (4)	29 Jan 2021 21:59:47

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:41:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:10:38
User closed query 'source = 05Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 16:10:36
Query 'source = 05Jan2021, please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	10 Feb 2021 19:26:54
User entered '05 Jan 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	10 Feb 2021 19:26:49
User opened query 'source = 05Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 14:14:47
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 14:14:26
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 14:14:16
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	29 Jan 2021 22:00:22

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:41:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:14:17
User entered 'BILATERAL THIGH LIFT'	Erica Osmundsen (b) (4)	29 Jan 2021 22:00:22

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:41:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:14:23
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	29 Jan 2021 22:00:22

US3202042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:41:24

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:14:25
User entered 'COSMETIC'	Erica Osmundsen (b) (4)	29 Jan 2021 22:00:22

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'USA-US128-2021-MRNA-1273-P301000005'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Mark'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'McKenzie'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'US'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	11 Feb 2021 19:55:18
User entered '7'	System	11 Feb 2021 19:53:12
User entered '6'	System	11 Feb 2021 17:53:21
User entered '5'	System	11 Feb 2021 17:06:35
User entered '4'	System	01 Feb 2021 13:22:25
User entered '3'	System	29 Jan 2021 13:27:38
User entered '2'	System	25 Jan 2021 19:43:35
User entered '1'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'USA-US128-2021-MRNA-1273-P301000005'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Mark'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'McKenzie'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'US'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	11 Feb 2021 19:55:18
User entered '7'	System	11 Feb 2021 19:53:12
User entered '6'	System	11 Feb 2021 17:53:21
User entered '5'	System	11 Feb 2021 17:06:35
User entered '4'	System	01 Feb 2021 13:22:25
User entered '3'	System	29 Jan 2021 13:27:38
User entered '2'	System	25 Jan 2021 19:43:35
User entered '1'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:41:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '12/Jan/2021 18:57'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:41:24

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.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'I'	(b) (4), (b) (6)	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'USA-US128-2021-MRNA-1273-P301000005'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Mark'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'McKenzie'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'US'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	11 Feb 2021 19:55:18
User entered '7'	System	11 Feb 2021 19:53:12
User entered '6'	System	11 Feb 2021 17:53:21
User entered '5'	System	11 Feb 2021 17:06:35
User entered '4'	System	01 Feb 2021 13:22:25
User entered '3'	System	29 Jan 2021 13:27:38
User entered '2'	System	25 Jan 2021 19:43:35
User entered '1'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:41:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
User entered '25/Jan/2021 19:43'	System	25 Jan 2021 19:43:35

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:41:24

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.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 19:43:35

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'USA-US128-2021-MRNA-1273-P301000005'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Mark'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'McKenzie'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'US'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	11 Feb 2021 19:55:18
User entered '7'	System	11 Feb 2021 19:53:12
User entered '6'	System	11 Feb 2021 17:53:21
User entered '5'	System	11 Feb 2021 17:06:35
User entered '4'	System	01 Feb 2021 13:22:25
User entered '3'	System	29 Jan 2021 13:27:38
User entered '2'	System	25 Jan 2021 19:43:35
User entered '1'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:41:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
User entered '29/Jan/2021 13:27'	System	29 Jan 2021 13:27:38

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:41:24

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.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:22:15
User entered 'I'	(b) (4), (b) (6)	29 Jan 2021 13:27:38

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'USA-US128-2021-MRNA-1273-P301000005'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Mark'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'McKenzie'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'US'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	11 Feb 2021 19:55:18
User entered '7'	System	11 Feb 2021 19:53:12
User entered '6'	System	11 Feb 2021 17:53:21
User entered '5'	System	11 Feb 2021 17:06:35
User entered '4'	System	01 Feb 2021 13:22:25
User entered '3'	System	29 Jan 2021 13:27:38
User entered '2'	System	25 Jan 2021 19:43:35
User entered '1'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:41:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
User entered '01/Feb/2021 13:22'	System	01 Feb 2021 13:22:25

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:41:24

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.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 17:42:34
User entered 'I'	(b) (4), (b) (6)	01 Feb 2021 13:22:25

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'USA-US128-2021-MRNA-1273-P301000005'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Mark'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'McKenzie'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'US'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	11 Feb 2021 19:55:18
User entered '7'	System	11 Feb 2021 19:53:12
User entered '6'	System	11 Feb 2021 17:53:21
User entered '5'	System	11 Feb 2021 17:06:35
User entered '4'	System	01 Feb 2021 13:22:25
User entered '3'	System	29 Jan 2021 13:27:38
User entered '2'	System	25 Jan 2021 19:43:35
User entered '1'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:41:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
User entered '11/Feb/2021 12:06'	System	11 Feb 2021 17:06:35

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:41:24

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.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 17:42:34
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 17:06:35

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'USA-US128-2021-MRNA-1273-P301000005'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Mark'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'McKenzie'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'US'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	11 Feb 2021 19:55:18
User entered '7'	System	11 Feb 2021 19:53:12
User entered '6'	System	11 Feb 2021 17:53:21
User entered '5'	System	11 Feb 2021 17:06:35
User entered '4'	System	01 Feb 2021 13:22:25
User entered '3'	System	29 Jan 2021 13:27:38
User entered '2'	System	25 Jan 2021 19:43:35
User entered '1'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:41:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
User entered '11/Feb/2021 12:53'	System	11 Feb 2021 17:53:21

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:41:24

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.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 17:53:21

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'USA-US128-2021-MRNA-1273-P301000005'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Mark'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'McKenzie'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'US'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	11 Feb 2021 19:55:18
User entered '7'	System	11 Feb 2021 19:53:12
User entered '6'	System	11 Feb 2021 17:53:21
User entered '5'	System	11 Feb 2021 17:06:35
User entered '4'	System	01 Feb 2021 13:22:25
User entered '3'	System	29 Jan 2021 13:27:38
User entered '2'	System	25 Jan 2021 19:43:35
User entered '1'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:41:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
User entered '11/Feb/2021 14:53'	System	11 Feb 2021 19:53:12

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:41:24

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.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 19:53:12

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'USA-US128-2021-MRNA-1273-P301000005'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Yes (Y)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'No (N)'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'Mark'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:38:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 18:57:01
User entered 'McKenzie'	System	12 Jan 2021 18:56:39

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:27:26
Un-reviewed for Safety.	System	25 Jan 2021 19:43:35
DataPoint Un-verified.	System	25 Jan 2021 19:43:35
User entered empty.	System	25 Jan 2021 19:43:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 13:23:24

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:43:20
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 20:38:01
User entered 'US'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	11 Feb 2021 19:55:18
User entered '7'	System	11 Feb 2021 19:53:12
User entered '6'	System	11 Feb 2021 17:53:21
User entered '5'	System	11 Feb 2021 17:06:35
User entered '4'	System	01 Feb 2021 13:22:25
User entered '3'	System	29 Jan 2021 13:27:38
User entered '2'	System	25 Jan 2021 19:43:35
User entered '1'	System	12 Jan 2021 18:57:08

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:41:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
User entered '11/Feb/2021 14:55'	System	11 Feb 2021 19:55:18

US3202042

Folder: SAE USA-US128-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:41:24

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.	Mark McKenzie (b) (4)	09 Apr 2021 13:18:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:46:00
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 19:55:18