

US3202304 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:45:32

All time stamps listed in this document are displayed in GMT

US3202304

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 16:00:32

Generated On: 09 Jun 2021 15:45:32

[Participant ID](#)

US3202304

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

US3202304

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:20:16

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:20:16

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Condition	IRREGULAR HEARTBEAT
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 (3)

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Condition	HEMORRHOIDS
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 (4)

Data signed: (b) (4) 13 Feb 2021 02:20:16

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Condition	ERECTILE DYSFUNCTION
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 (8)

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN JAN 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Condition	HYPOGONADISM
Start date (dd MMM yyyy)	UN UNK 1962
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 1962
Start Year (derived)	1962
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 02:20:16

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Condition	HYPERTENSION (BORDERLINE)
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:52 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 13:52
Height (<i>xxx.x</i>)	192.4 cm
Weight (<i>xxx.x</i>)	127.4 kg
BMI (<i>xxx.x</i>)	34.41591 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 02:20:16

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:20:16

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:20:16

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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 02:20:17

Generated On: 09 Jun 2021 15:45:32

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 188688

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:20:17

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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 02:20:17

Generated On: 09 Jun 2021 15:45:32

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)	28 AUG 2020
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 13:40
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

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)	28 AUG 2020
Time of assessment (00:00-23:59)	15:16 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:16
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

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 02:20:16

Generated On: 09 Jun 2021 15:45:32

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 14:33 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 14:33

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 02:20:17

Generated On: 09 Jun 2021 15:45:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 AUG 2020
Collection time (00:00-23:59)	13:57 (24 HR)
Collection date and time (derived)	28 AUG 2020 13:57

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:55	28 AUG 2020 13:55
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 14:54

PC Open Date & Time

28 AUG 2020 14:53

PC Close Date & Time

28 AUG 2020 17:23

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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 98.1 °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	28 AUG 2020 18:18
PC Open Date & Time	28 AUG 2020 18:18
PC Close Date & Time	29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 29 AUG 2020 12:13

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

30 AUG 2020 12:02

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

31 AUG 2020 12:14

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

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

01 SEP 2020 12:04

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

98.5 °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

02 SEP 2020 12:43

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

03 SEP 2020 12:16

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

28 AUG 2020 14:55

PC Open Date & Time

28 AUG 2020 14:53

PC Close Date & Time

28 AUG 2020 17:23

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

28 AUG 2020 18:19

PC Open Date & Time

28 AUG 2020 18:18

PC Close Date & Time

29 AUG 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

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

29 AUG 2020 12:14

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

30 AUG 2020 12:03

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

31 AUG 2020 12:14

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

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

01 SEP 2020 12:05

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

02 SEP 2020 12:43

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

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

03 SEP 2020 12:17

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 14:55
PC Open Date & Time	28 AUG 2020 14:53
PC Close Date & Time	28 AUG 2020 17:23

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 18:19
PC Open Date & Time	28 AUG 2020 18:18
PC Close Date & Time	29 AUG 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

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 ☒

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:14
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

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EAB) (1725)

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:04
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

EAB) (1725)

52 of 2333

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:15
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

54 of 2333

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:06
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

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 ☒

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 12:44
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

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 ☒

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:17
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3202304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments LVM

If Contact Not Made, please provide Comments

US3202304

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments LVM

If Contact Not Made, please provide Comments

US3202304

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202304

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

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)	25 SEP 2020
Time of assessment (00:00-23:59)	09:16 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 09:16
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

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)	25 SEP 2020
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 10:37
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3202304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

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.

US3202304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

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) 25 SEP 2020

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

Treatment Date and Time (derived) 25 SEP 2020 10:00

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

US3202304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 SEP 2020

Collection time (00:00-23:59)

09:26 (24 HR)

Collection date and time (derived)

25 SEP 2020 09:26

US3202304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:24	25 SEP 2020 09:24
Nasopharyngeal Swab 2	No		

US3202304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp 25 SEP 2020 10:34

PC Open Date & Time 25 SEP 2020 10:20

PC Close Date & Time 25 SEP 2020 12:50

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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	25 SEP 2020 14:26
PC Open Date & Time	25 SEP 2020 13:45
PC Close Date & Time	26 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

26 SEP 2020 15:35

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 12:08

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

96.7 °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

28 SEP 2020 12:06

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 12:21

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 12:19

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 12:01

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

25 SEP 2020 10:35

PC Open Date & Time

25 SEP 2020 10:20

PC Close Date & Time

25 SEP 2020 12:50

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

25 SEP 2020 14:27

PC Open Date & Time

25 SEP 2020 13:45

PC Close Date & Time

26 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

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

26 SEP 2020 15:35

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

27 SEP 2020 12:08

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

28 SEP 2020 12:06

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

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

29 SEP 2020 12:21

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

30 SEP 2020 12:19

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

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

01 OCT 2020 12:02

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 10:35
PC Open Date & Time	25 SEP 2020 10:20
PC Close Date & Time	25 SEP 2020 12:50

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 14:28
PC Open Date & Time	25 SEP 2020 13:45
PC Close Date & Time	26 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

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 ☒

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 15:36
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

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 ☒

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 12:09
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

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 ☒

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 12:06
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:21
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

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 ☒

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 12:20
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

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 ☒

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202304

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 OCT 2020

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

Comments LVM ATTEMPTS X3

If Contact Not Made, please provide Comments

US3202304

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:45:20

Generated On: 09 Jun 2021 15:45:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 OCT 2020

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

Comments X 3 ATTEMPTS

If Contact Not Made, please provide Comments

US3202304

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:20:16

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	09:01 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 09:01
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202304

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

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.

US3202304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 OCT 2020
Collection time (00:00-23:59)	09:11 (24 HR)
Collection date and time (derived)	23 OCT 2020 09:11

US3202304

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:20:17

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 10:58:15
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 08:46:12
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 11:56:20

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 08:11:58

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 <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	21 DEC 2020 09:08:15
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 <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"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 16:14:23

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 09:42:15

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

17 JAN 2021 12:07:54

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 152

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

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 09:19:45

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 07:58:31

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 09:14:48

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 09:36:50

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

02 MAR 2021 12:45:34

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 12:01:11

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

21 MAR 2021 09:10:38

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 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	07 APR 2021 18:00:53
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

13 APR 2021 12:00:36

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 09:17:24

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

02 MAY 2021 09:37:31

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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="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"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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°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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 SEP 2021 00:01
Patient Cloud Close Date & Time	23 SEP 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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="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"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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="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"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 MAR 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐ Yes ☐

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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"/>

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3202304

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:45:32

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		02 MAR 2021 12:45:49

US3202304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:51:06

Generated On: 09 Jun 2021 15:45:32

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments LEFT MESSAGE FOR DAY 85
PHONE CALL

If Contact Not Made, please provide Comments

SUB CALLED BACK LATER ON
20 NOV 2020

US3202304

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:51:06

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202304

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202304

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

COMPLETED WITH OL-DOSE 2

If Contact Not Made, please provide Comments

US3202304

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

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

Visit date (dd MMM yyyy)	25 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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US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

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) _____

US3202304

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

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.

US3202304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	11:55 (24 HR)
Collection date and time (derived)	25 MAR 2021 11:55

US3202304

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3202304

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:45:32

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"/>

US3202304

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:45:32

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3202304

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

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

Visit date (dd MMM yyyy)	26 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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US3202304

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 18:01:32

Generated On: 09 Jun 2021 15:45:32

Date of updated informed consent (<i>dd MMM yyyy</i>)	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3202304

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Height	
Weight	
BMI (xxx.x)	

US3202304

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Height	
Weight	
BMI (xxx.x)	
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)	26 JAN 2021
Time of assessment (00:00-23:59)	09:36 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 09:36
Temperature (xxx.x)	37 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3202304

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 10:26
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3202304

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

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

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.

US3202304

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

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 26 JAN 2021

What was the treatment time? (00:00-23:59) 09:51 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 09:51

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

US3202304

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

09:49 (24 HR)

Collection date and time (derived)

26 JAN 2021 09:49

US3202304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	09:47
Collection Date and Time (derived)	26 JAN 2021 09:47

US3202304

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

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202304

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

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

Visit date (dd MMM yyyy)	23 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

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)	23 FEB 2021
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 10:05
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)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	11:03 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 11:03
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3202304

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

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.

US3202304

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 10:28 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 10:28

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

US3202304

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202304

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202304

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 13:43:15

Generated On: 09 Jun 2021 15:45:32

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

Visit date (dd MMM yyyy)	25 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 13:43:15

Generated On: 09 Jun 2021 15:45:32

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) _____

US3202304

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 13:43:15

Generated On: 09 Jun 2021 15:45:32

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.

US3202304

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 13:43:15

Generated On: 09 Jun 2021 15:45:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	11:55 (24 HR)
Collection date and time (derived)	25 MAR 2021 11:55

US3202304

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 13:14:46

Generated On: 09 Jun 2021 15:45:32

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

AEID USA-US128-2020-MRNA-1273-P30
1000015

Adverse event WORSENING OF ENLARGED
PROSTATE (BENIGN PROSTATIC
HYPERPLASIA)

Was this a medically-attended AE? Yes ☒
No ☐

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 01 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 18 DEC 2020

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 True

Hospital Admission Date (dd MMM yyyy) 17 DEC 2020

Hospital Discharge Date (dd MMM yyyy) 18 DEC 2020

Admitted to ICU? Yes ☐
No ☒

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

	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		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"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
Narrative	SUBJECT REPORTED HAVING PROSTATECTOMY DUE TO WORSENING OF THIS CONDITION. WAS KEPT IN HOSPITAL OVERNIGHT	
<hr/>		
Serious Adverse Event Derived (CSA Programming Field Only)		1
<hr/>		
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

AEID

Adverse event

STREP THROAT

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)

28 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

6 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) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

AEID

Adverse event

LACERATIONS TO BOTH
HANDS

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)

14 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)

14 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 ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

AEID

Adverse event

SYNCOPE (HYPOTENSIVE
EPISODE)

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)

14 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)

14 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 ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

AEID	
Adverse event	RIGHT KNEE PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication ENLARGED PROSTATE

Dose per administration 0.8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

	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 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 DEC 2020	
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 (3)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication CIALIS

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication TESTOSTERONE PELLETS

Prophylaxis Yes ☐
No ☒

Indication HYPOGONADISM

Dose per administration 10

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

If dose unit is Other, specify PELLETS

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

If frequency is Other, specify EVERY 3 MONTHS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication	FLU VAC
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	FLU PREVENTION
Dose per administration	0.5
Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication OXYBUTYNIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS OF BLADDER
SPASMS
POST-PROSTATECTOMY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

	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)	17 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication CEPHALEXIN

Prophylaxis Yes ☐
No ☒

Indication LACERATION TO BOTH HANDS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

	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)		14 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) 24 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication DOCUSATE

Prophylaxis Yes ☒
No ☐

Indication PREVENT CONSTIPATION POST
OP

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

	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)	17 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication POST OP PAIN

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

	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)		17 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 20 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication BACTRIM DS

Prophylaxis Yes ☒
No ☐

Indication PREVENT POST OP INFECTION

Dose per administration 800/160

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

	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)		17 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication AMOXIL

Prophylaxis Yes ☐
No ☒

Indication STREP INFECTION- THROAT

Dose per administration 875

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) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

	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)	28 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		6 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication BORDERLINE HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 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"/>

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 19:21:30

Generated On: 09 Jun 2021 15:45:32

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

US3202304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
17 DEC 2020	PROSTATECTOMY COMPLETE LASER ENUCLEATION OF PROSTATE	Adverse Event	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:45:32

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 ☐

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

SAEID	USA-US128-2020-MRNA-1273-P301000015
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)	4

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

SAEID	USA-US128-2020-MRNA-1273-P301000015
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)	4
Date of submission (Pre-filled from custom function)	23/DEC/2020 09:36
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

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Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

SAEID	USA-US128-2020-MRNA-1273-P301000015
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)	4
Date of submission (Pre-filled from custom function)	27/JAN/2021 12:34
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

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

SAEID	USA-US128-2020-MRNA-1273-P301000015
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)	4
Date of submission (Pre-filled from custom function)	09/FEB/2021 13:05
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

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 16:00:33

Generated On: 09 Jun 2021 15:45:32

SAEID	USA-US128-2020-MRNA-1273-P301000015
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)	4
Date of submission (Pre-filled from custom function)	12/FEB/2021 11:34
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

US3202304 (Prod: WR-ClinSearch, LLC)

US3202304

Form: Participant Creation

Generated On: 09 Jun 2021 15:45:32

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:48:10
User entered 'US3202304'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:34:50

US3202304

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:21:53
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:05:52

US3202304

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:21:53
User closed query 'source = 24 AUG please verify' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:21:49
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	18 Nov 2020 02:10:39
Query 'source = 24 AUG please verify' answered with 'corrected per source' (Site from CRA).	Erica Osmundsen (b) (4)	18 Nov 2020 02:10:18
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	18 Nov 2020 02:10:00
User entered '24 Aug 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	18 Nov 2020 02:10:00
User opened query 'source = 24 AUG please verify' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:46:59
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	31 Aug 2020 12:54:40
User entered '28 Aug 2020' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	31 Aug 2020 12:54:40
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	28 Aug 2020 18:06:05
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:34:51

US3202304

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:21:53
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:05:52

US3202304

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered 'SCRN'	System	28 Aug 2020 18:05:52

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered (b) (6) 1944'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:34:52

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered '76'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered 'YEARS'	System	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered '76'	System	28 Aug 2020 18:06:05

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered 'Male (M)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered 'I'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:32

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:18
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:28:15

US3202304

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:32

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:20:20
User closed query 'source = 24 Aug please verify' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:20:14
Query 'source = 24 Aug please verify' answered with 'corrected per source' (Site from CRA).	Erica Osmundsen (b) (4)	18 Nov 2020 02:10:54
User entered '24 Aug 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	18 Nov 2020 02:10:39
User opened query 'source = 24 Aug please verify' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:50:35
User entered '28 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:06:05

US3202304

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered 'Aug 2020'	System	28 Aug 2020 18:06:05

US3202304

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered '2020'	System	28 Aug 2020 18:06:05

US3202304

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:32

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:37
User entered 'Amendment 3 (3)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:06:05

US3202304

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:39
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:06:05

US3202304

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:41
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:06:05

US3202304

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:32

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:43
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:06:05

US3202304

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:32

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:47
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:06:05

US3202304

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:32

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:48
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 17:34:51

US3202304

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:32

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered 'I'	System	28 Aug 2020 18:06:10

US3202304

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:20
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:06:10

US3202304

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:45:32

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:59:20
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:29:47

US3202304

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Heart rate and pulse investigations, PT: Heart rate irregular, LLT: Heartbeats irregular - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:32:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:32:00
Data point term sent to Coder	System	31 Aug 2020 12:30:59
User entered 'Irregular Heartbeat'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:30:57

US3202304

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:30:57

US3202304

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered 'l'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:30:57

US3202304

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:30:57

US3202304

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:30:57

US3202304

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:30:57

US3202304

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:30:57

US3202304

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:30:57

US3202304

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:30:57

US3202304

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:30:57

US3202304

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:32:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:32:44
Data point term sent to Coder	System	31 Aug 2020 12:32:00
User entered 'Hemorrhoids'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:31:37

US3202304

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:31:37

US3202304

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered 'I'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:31:37

US3202304

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:31:37

US3202304

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:31:37

US3202304

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:31:37

US3202304

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:31:37

US3202304

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:31:37

US3202304

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:31:37

US3202304

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:31:37

US3202304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:37:59
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 21:41:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 21:41:53
Data point term sent to Coder	System	22 Dec 2020 21:41:15
DataPoint Un-verified.	Erica Osmundsen (b) (4)	22 Dec 2020 21:40:40
Coding entries removed.	Erica Osmundsen (b) (4)	22 Dec 2020 21:40:40
User entered 'ENLARGED PROSTATE (BENIGN PROSTATIC HYPERPLASIA)' reason for change:	Erica Osmundsen (b) (4)	22 Dec 2020 21:40:40
Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 20:53:25
DataPoint Verified.	(b) (4), (b) (6)	
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:33:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:33:45
Data point term sent to Coder	System	31 Aug 2020 12:33:01
User entered 'Enlarged prostate'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:32:23

US3202304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered 'UN UNK 2004'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:32:23

US3202304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:32:23

US3202304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:32:23

US3202304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:32:23

US3202304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:32:23

US3202304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered 'Jan 2004'	System	31 Aug 2020 12:32:23

US3202304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered '2004'	System	31 Aug 2020 12:32:23

US3202304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:32:23

US3202304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:32:23

US3202304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:33:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:33:45
Data point term sent to Coder	System	31 Aug 2020 12:33:01
User entered 'Erectile dysfunction'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:32:43

US3202304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:32:43

US3202304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered 'I'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:32:43

US3202304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:32:43

US3202304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:32:43

US3202304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:32:43

US3202304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:32:43

US3202304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:32:43

US3202304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:32:43

US3202304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:32:43

US3202304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:36:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:36:48
Data point term sent to Coder	System	31 Aug 2020 12:36:06
User entered 'Depression'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:35:33

US3202304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered 'UN Jan 2019' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	28 Sep 2020 14:49:32
User entered 'UN Jun 2019'	(b) (4) Tiffany Jewell (b) (4)	31 Aug 2020 12:35:33

US3202304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:35:33

US3202304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:35:33

US3202304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:35:33

US3202304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:35:33

US3202304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered 'Jan 2019'	System	28 Sep 2020 14:49:32
User entered 'Jun 2019'	System	31 Aug 2020 12:35:33

US3202304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered '2019'	System	31 Aug 2020 12:35:33

US3202304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:35:33

US3202304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:35:33

US3202304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User coded data point as SOC: Endocrine disorders, HLGT: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Hypogonadism, LLT: Hypogonadism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:39:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:39:46
Data point term sent to Coder	System	31 Aug 2020 12:39:08
User entered 'Hypogonadism'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:38:31

US3202304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered 'UN UNK 1962'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:38:31

US3202304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:38:31

US3202304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:38:31

US3202304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:38:31

US3202304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:25
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:38:31

US3202304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered 'Jan 1962'	System	31 Aug 2020 12:38:31

US3202304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered '1962'	System	31 Aug 2020 12:38:31

US3202304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:38:31

US3202304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	31 Aug 2020 12:38:31

US3202304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:08:30
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Borderline hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 14:45:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 14:45:33
Data point term sent to Coder	System	08 Feb 2021 14:45:04
User entered 'hypertension (borderline)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:44:40

US3202304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:08:30
User entered 'un UNK 2018'	Erica Osmundsen (b) (4)	08 Feb 2021 14:44:40

US3202304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:08:30
User entered '0'	Erica Osmundsen (b) (4)	08 Feb 2021 14:44:40

US3202304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:08:30
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:44:40

US3202304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:08:30
User entered empty.	Erica Osmundsen (b) (4)	08 Feb 2021 14:44:40

US3202304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:08:30
User entered '0'	Erica Osmundsen (b) (4)	08 Feb 2021 14:44:40

US3202304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered 'Jan 2018'	System	08 Feb 2021 14:44:40

US3202304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered '2018'	System	08 Feb 2021 14:44:40

US3202304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	08 Feb 2021 14:44:40

US3202304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User entered empty.	System	08 Feb 2021 14:44:40

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:58:04
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:22:09
User closed query 'source = 24 Aug please verify' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:22:05
Query 'source = 24 Aug please verify' answered with 'corrected per source' (Site from CRA).	Erica Osmundsen (b) (4)	18 Nov 2020 02:11:17
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Nov 2020 02:11:10
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	18 Nov 2020 02:11:10
User entered '24 Aug 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	18 Nov 2020 02:11:10
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Nov 2020 02:10:00
User opened query 'source = 24 Aug please verify' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:57:59
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 12:54:40
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	31 Aug 2020 12:54:40
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 12:54:17
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	31 Aug 2020 12:54:17
User entered '28 Aug 2020' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:54:17
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	31 Aug 2020 12:51:55

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:58:06
User entered '13:52'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User entered '24 Aug 2020 13:52'	System	18 Nov 2020 02:11:10
User entered '28 Aug 2020 13:52'	System	31 Aug 2020 12:54:17
User entered '24 Aug 2020 13:52'	System	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:58:09
User entered '192.4' cm	Tiffany Jewell (b) (4)	31 Aug 2020 12:51:55
DataPoint set to visible.	(b) (4) System	28 Aug 2020 18:06:10

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:58:12
User entered '127.4' kg	Tiffany Jewell (b) (4)	31 Aug 2020 12:51:55
DataPoint set to visible.	(b) (4) System	28 Aug 2020 18:06:10

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User entered '34.41591'	System	31 Aug 2020 12:51:55
DataPoint set to visible.	System	28 Aug 2020 18:06:10

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User entered 'kg/m2'	System	31 Aug 2020 12:51:55
DataPoint set to visible.	System	28 Aug 2020 18:06:10

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:58:13
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:53:45
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)	19 Dec 2020 09:17:05
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 21:03:50
DataPoint Un-verified.	zackery harmon (b) (4) (b) (4)	15 Dec 2020 21:03:45
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4) (b) (4)	15 Dec 2020 21:03:45
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 16:17:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:58:16
User entered 'Other (Other)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:58:17
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:58:19
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
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)	30 Apr 2021 15:05:13
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 19:33:26
User entered 'bpm'	System	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:58:21
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
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)	30 Apr 2021 15:05:14
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 19:33:35
User entered 'breaths/min'	System	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:58:23
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
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)	30 Apr 2021 15:05:15
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 19:33:56
User entered 'mmHg'	System	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:58:24
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
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)	30 Apr 2021 15:05:17
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 19:34:16
User entered 'mmHg'	System	31 Aug 2020 12:51:55

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43

US3202304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43

US3202304

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:00:46
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:55:27

US3202304

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:20:44
User closed query 'source =24 Aug please verify' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:20:41
Query 'source =24 Aug please verify' answered with 'corrected per source' (Site from CRA).	Erica Osmundsen (b) (4)	18 Nov 2020 02:11:29
User entered '24 Aug 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	18 Nov 2020 02:11:24
User opened query 'source =24 Aug please verify' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:01:07
User entered '28 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:55:27

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

[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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

[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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

[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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

[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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
User entered '0'	Tiffany Jewell (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

[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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

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 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:28
User entered 'I'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
User entered '1' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 02:16:08
User entered '0'	Tiffany Jewell (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:47
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:53:09
User closed query 'please provide high-risk sociodemographic factors' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:21:02
User closed query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	18 Nov 2020 02:16:08
Query 'please provide high-risk sociodemographic factors' answered with 'done' (Site from CRA).	Erica Osmundsen (b) (4)	18 Nov 2020 02:16:00
User opened query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	18 Nov 2020 02:15:52
User entered 'regularly attends places where large groups gather (church, volunteer meetings, grocery store)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	18 Nov 2020 02:15:52
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:34
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:28
User opened query 'please provide high-risk sociodemographic factors' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:03:55
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:56:36

US3202304

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:46
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:06:21

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:46
User entered '28 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:06:21

US3202304

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

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 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:06:46
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:06:21

US3202304

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'VISIT1'	System	28 Aug 2020 18:06:21

US3202304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:13
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:59:54

US3202304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:32

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:13
User entered '188688'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:59:54

US3202304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:32

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:13
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:59:54

US3202304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:32

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 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:13
Query ' PER CDM: Please complete this section of the form' canceled (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 17:48:43
User opened query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 17:48:29
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:57:13

US3202304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:32

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 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:13
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:57:13

US3202304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:32

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:13
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:57:13

US3202304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:32

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:13
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:57:13

US3202304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:32

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:13
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:57:13

US3202304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:32

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:13
User entered 'No (N)'	Tiffany Jewell (b) (4)	25 Sep 2020 13:55:20
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 02:41:49
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:41:47

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '28 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '13:40'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '28 Aug 2020 13:40'	System	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '37.0' C	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered 'Oral (Oral)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '70'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'bpm'	System	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '14'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'breaths/min'	System	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '123'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'mmHg'	System	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '76'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'mmHg'	System	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '28 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '15:16'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '28 Aug 2020 15:16'	System	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '36.7' C	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered 'Oral (Oral)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '76'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'bpm'	System	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '18'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'breaths/min'	System	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '135'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'mmHg'	System	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:06
User entered '76'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'mmHg'	System	31 Aug 2020 12:59:35

US3202304

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:13
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:47

US3202304

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:13
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:59:47

US3202304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:27
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:43:44

US3202304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:27
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:43:44

US3202304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

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 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:27
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:43:44

US3202304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 18:43:44

US3202304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:27
User entered '28 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:43:44

US3202304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:27
User entered '14:33'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:43:44

US3202304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '28 Aug 2020 14:33'	System	28 Aug 2020 18:43:44

US3202304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:09:27
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:43:44

US3202304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:09:27
User entered 'ONCE'	System	28 Aug 2020 18:43:44

US3202304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 18:43:44

US3202304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:09
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 18:44:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 18:44:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:44:31
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 18:44:27
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:44:27

US3202304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:09
User entered '28 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:44:27

US3202304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:09
User entered '13:57'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:44:27

US3202304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '28 Aug 2020 13:57'	System	28 Aug 2020 18:44:27

US3202304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:45:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:33
User entered '28 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:44:52

US3202304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	28 Aug 2020 18:44:52

US3202304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:33
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:44:52

US3202304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:33
User entered '13:55'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:44:52

US3202304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '28 Aug 2020 13:55'	System	28 Aug 2020 18:44:52

US3202304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	28 Aug 2020 18:44:52

US3202304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:33
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:44:52

US3202304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:33
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:44:52

US3202304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered empty.	System	28 Aug 2020 18:44:52

US3202304

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:43
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	28 Aug 2020 18:43:51

US3202304

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'I'	System	28 Aug 2020 18:43:51

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:54:23', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'd3dacf91-a0e6-46b7-a470-0d347351921d'	System	28 Aug 2020 18:54:49
User entered 'Yes (Y)'	System	28 Aug 2020 18:54:49

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:54:32', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'd3dacf91-a0e6-46b7-a470-0d347351921d'	System	28 Aug 2020 18:54:49
User entered '98.6'	System	28 Aug 2020 18:54:49

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:54:37', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'd3dacf91-a0e6-46b7-a470-0d347351921d'	System	28 Aug 2020 18:54:49
User entered 'No (N)'	System	28 Aug 2020 18:54:49

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:54:45', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'd3dacf91-a0e6-46b7-a470-0d347351921d'	System	28 Aug 2020 18:54:49
User entered '28 Aug 2020 14:54'	System	28 Aug 2020 18:54:49

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '28 Aug 2020 14:53'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '28 Aug 2020 17:23'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:18:27', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '936a6ba6-6f5b-4e3b-8f07-f36b8d3b3509'	System	28 Aug 2020 22:18:50
User entered 'Yes (Y)'	System	28 Aug 2020 22:18:50

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:18:35', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '936a6ba6-6f5b-4e3b-8f07-f36b8d3b3509'	System	28 Aug 2020 22:18:50
User entered '98.1'	System	28 Aug 2020 22:18:50

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:18:39', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '936a6ba6-6f5b-4e3b-8f07-f36b8d3b3509'	System	28 Aug 2020 22:18:50
User entered 'No (N)'	System	28 Aug 2020 22:18:50

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:18:46', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '936a6ba6-6f5b-4e3b-8f07-f36b8d3b3509'	System	28 Aug 2020 22:18:50
User entered '28 Aug 2020 18:18'	System	28 Aug 2020 22:18:50

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '28 Aug 2020 18:18'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 2'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:13:41', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'db9257bb-17d3-4145-8feb-aedc19c3faae'	System	29 Aug 2020 16:13:53
User entered 'No (N)'	System	29 Aug 2020 16:13:53

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:13:45', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'db9257bb-17d3-4145-8feb-aedc19c3faae'	System	29 Aug 2020 16:13:53
User entered 'No (N)'	System	29 Aug 2020 16:13:53

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:13:51', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'db9257bb-17d3-4145-8feb-aedc19c3faae'	System	29 Aug 2020 16:13:53
User entered '29 Aug 2020 12:13'	System	29 Aug 2020 16:13:53

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 3'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:02:24', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '8d42f711-f446-4dd2-9e8d-73b997fa1ab8'	System	30 Aug 2020 16:03:18
User entered 'Yes (Y)'	System	30 Aug 2020 16:03:18

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:02:32', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '8d42f711-f446-4dd2-9e8d-73b997fa1ab8'	System	30 Aug 2020 16:03:18
User entered '98.0'	System	30 Aug 2020 16:03:18

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:02:38', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '8d42f711-f446-4dd2-9e8d-73b997fa1ab8'	System	30 Aug 2020 16:03:18
User entered 'No (N)'	System	30 Aug 2020 16:03:18

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:02:43', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '8d42f711-f446-4dd2-9e8d-73b997fa1ab8'	System	30 Aug 2020 16:03:18
User entered '30 Aug 2020 12:02'	System	30 Aug 2020 16:03:18

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 4'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:14:23', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6180ef81-6571-4999-be6b-c318d5fe560c'	System	31 Aug 2020 16:24:36
User entered 'Yes (Y)'	System	31 Aug 2020 16:24:36

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:14:30', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6180ef81-6571-4999-be6b-c318d5fe560c'	System	31 Aug 2020 16:24:36
User entered '98.2'	System	31 Aug 2020 16:24:36

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:14:36', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6180ef81-6571-4999-be6b-c318d5fe560c'	System	31 Aug 2020 16:24:36
User entered 'No (N)'	System	31 Aug 2020 16:24:36

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:14:40', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6180ef81-6571-4999-be6b-c318d5fe560c'	System	31 Aug 2020 16:24:36
User entered '31 Aug 2020 12:14'	System	31 Aug 2020 16:24:36

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 5'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:04:12', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '065ad98f-7906-468a-b3a4-2f7d5f7febfd'	System	01 Sep 2020 16:04:51
User entered 'Yes (Y)'	System	01 Sep 2020 16:04:51

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:04:35', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '065ad98f-7906-468a-b3a4-2f7d5f7febfd'	System	01 Sep 2020 16:04:51
User entered '97.9'	System	01 Sep 2020 16:04:51

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:04:39', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '065ad98f-7906-468a-b3a4-2f7d5f7febfd'	System	01 Sep 2020 16:04:51
User entered 'No (N)'	System	01 Sep 2020 16:04:51

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:04:45', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '065ad98f-7906-468a-b3a4-2f7d5f7febfd'	System	01 Sep 2020 16:04:51
User entered '01 Sep 2020 12:04'	System	01 Sep 2020 16:04:51

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 6'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:42:47', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a8ff5320-a249-4c39-9d42-5d354e5bdd7f'	System	02 Sep 2020 16:43:10
User entered 'Yes (Y)'	System	02 Sep 2020 16:43:10

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:42:58', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a8ff5320-a249-4c39-9d42-5d354e5bdd7f' User entered '98.5'	System	02 Sep 2020 16:43:10

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:02', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a8ff5320-a249-4c39-9d42-5d354e5bdd7f'	System	02 Sep 2020 16:43:10
User entered 'No (N)'	System	02 Sep 2020 16:43:10

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:06', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a8ff5320-a249-4c39-9d42-5d354e5bdd7f'	System	02 Sep 2020 16:43:10
User entered '02 Sep 2020 12:43'	System	02 Sep 2020 16:43:10

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 7'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:15:17', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '94fdc8c9-cca9-418e-9d84-22c8385461ec'	System	03 Sep 2020 16:16:55
User entered 'Yes (Y)'	System	03 Sep 2020 16:16:55

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:16:43', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '94fdc8c9-cca9-418e-9d84-22c8385461ec'	System	03 Sep 2020 16:16:55
User entered '97.2'	System	03 Sep 2020 16:16:55

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:16:48', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '94fdc8c9-cca9-418e-9d84-22c8385461ec'	System	03 Sep 2020 16:16:55
User entered 'No (N)'	System	03 Sep 2020 16:16:55

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:16:52', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '94fdc8c9-cca9-418e-9d84-22c8385461ec'	System	03 Sep 2020 16:16:55
User entered '03 Sep 2020 12:16'	System	03 Sep 2020 16:16:55

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:54:56', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '696be925-5602-4452-9640-481eea63b355'	System	28 Aug 2020 18:55:19
User entered 'None (1)'	System	28 Aug 2020 18:55:19

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:55:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '696be925-5602-4452-9640-481eea63b355'	System	28 Aug 2020 18:55:19
User entered 'No (N)'	System	28 Aug 2020 18:55:19

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:55:03', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '696be925-5602-4452-9640-481eea63b355'	System	28 Aug 2020 18:55:19
User entered 'No (N)'	System	28 Aug 2020 18:55:19

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:55:09', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '696be925-5602-4452-9640-481eea63b355'	System	28 Aug 2020 18:55:19
User entered 'None (1)'	System	28 Aug 2020 18:55:19

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:55:15', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '696be925-5602-4452-9640-481eea63b355'	System	28 Aug 2020 18:55:19
User entered '28 Aug 2020 14:55'	System	28 Aug 2020 18:55:19

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '28 Aug 2020 14:53'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '28 Aug 2020 17:23'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:18:52', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9e624dfa-f99b-470e-8c5d-69bb1fe09cf2'	System	28 Aug 2020 22:19:12
User entered 'None (1)'	System	28 Aug 2020 22:19:12

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:18:55', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9e624dfa-f99b-470e-8c5d-69bb1fe09cf2'	System	28 Aug 2020 22:19:12
User entered 'No (N)'	System	28 Aug 2020 22:19:12

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:18:59', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9e624dfa-f99b-470e-8c5d-69bb1fe09cf2'	System	28 Aug 2020 22:19:12
User entered 'No (N)'	System	28 Aug 2020 22:19:12

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:19:02', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9e624dfa-f99b-470e-8c5d-69bb1fe09cf2'	System	28 Aug 2020 22:19:12
User entered 'None (1)'	System	28 Aug 2020 22:19:12

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:19:09', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9e624dfa-f99b-470e-8c5d-69bb1fe09cf2'	System	28 Aug 2020 22:19:12
User entered '28 Aug 2020 18:19'	System	28 Aug 2020 22:19:12

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '28 Aug 2020 18:18'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 2'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:13:58', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '28b1988f-09bc-4f57-9d7b-a66c5af4d4f6'	System	29 Aug 2020 16:14:18
User entered 'None (1)'	System	29 Aug 2020 16:14:18

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:14:01', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '28b1988f-09bc-4f57-9d7b-a66c5af4d4f6'	System	29 Aug 2020 16:14:18
User entered 'No (N)'	System	29 Aug 2020 16:14:18

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:14:04', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '28b1988f-09bc-4f57-9d7b-a66c5af4d4f6'	System	29 Aug 2020 16:14:18
User entered 'No (N)'	System	29 Aug 2020 16:14:18

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:14:08', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '28b1988f-09bc-4f57-9d7b-a66c5af4d4f6'	System	29 Aug 2020 16:14:18
User entered 'None (1)'	System	29 Aug 2020 16:14:18

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:14:14', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '28b1988f-09bc-4f57-9d7b-a66c5af4d4f6'	System	29 Aug 2020 16:14:18
User entered '29 Aug 2020 12:14'	System	29 Aug 2020 16:14:18

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 3'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:02:49', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f73b9148-4cf8-42ad-bd10-d0407dcebb20'	System	30 Aug 2020 16:03:46
User entered 'None (1)'	System	30 Aug 2020 16:03:46

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:03:12', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f73b9148-4cf8-42ad-bd10-d0407dcebb20'	System	30 Aug 2020 16:03:46
User entered 'No (N)'	System	30 Aug 2020 16:03:46

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:03:15', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f73b9148-4cf8-42ad-bd10-d0407dcebb20'	System	30 Aug 2020 16:03:46
User entered 'No (N)'	System	30 Aug 2020 16:03:46

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:03:21', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f73b9148-4cf8-42ad-bd10-d0407dcebb20'	System	30 Aug 2020 16:03:46
User entered 'None (1)'	System	30 Aug 2020 16:03:46

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:03:26', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f73b9148-4cf8-42ad-bd10-d0407dcebb20'	System	30 Aug 2020 16:03:46
User entered '30 Aug 2020 12:03'	System	30 Aug 2020 16:03:46

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 4'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:14:46', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '96b7192f-f806-49e5-adb1-d643f82926a4'	System	31 Aug 2020 16:24:47
User entered 'None (1)'	System	31 Aug 2020 16:24:47

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:14:49', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '96b7192f-f806-49e5-adb1-d643f82926a4'	System	31 Aug 2020 16:24:47
User entered 'No (N)'	System	31 Aug 2020 16:24:47

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:14:52', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '96b7192f-f806-49e5-adb1-d643f82926a4'	System	31 Aug 2020 16:24:47
User entered 'No (N)'	System	31 Aug 2020 16:24:47

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:14:55', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '96b7192f-f806-49e5-adb1-d643f82926a4'	System	31 Aug 2020 16:24:47
User entered 'None (1)'	System	31 Aug 2020 16:24:47

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:14:58', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '96b7192f-f806-49e5-adb1-d643f82926a4'	System	31 Aug 2020 16:24:47
User entered '31 Aug 2020 12:14'	System	31 Aug 2020 16:24:47

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 5'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:05:06', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '91255728-bac1-4dc1-be33-2aeced59e1c1'	System	01 Sep 2020 16:05:31
User entered 'None (1)'	System	01 Sep 2020 16:05:31

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:05:10', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '91255728-bac1-4dc1-be33-2aeced59e1c1'	System	01 Sep 2020 16:05:31
User entered 'No (N)'	System	01 Sep 2020 16:05:31

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:05:13', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '91255728-bac1-4dc1-be33-2aeced59e1c1'	System	01 Sep 2020 16:05:31
User entered 'No (N)'	System	01 Sep 2020 16:05:31

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:05:17', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '91255728-bac1-4dc1-be33-2aeced59e1c1'	System	01 Sep 2020 16:05:31
User entered 'None (1)'	System	01 Sep 2020 16:05:31

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:05:27', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '91255728-bac1-4dc1-be33-2aeced59e1c1'	System	01 Sep 2020 16:05:31
User entered '01 Sep 2020 12:05'	System	01 Sep 2020 16:05:31

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 6'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:12', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9fdb8ebd-4239-43ab-96bd-00235ada31dc'	System	02 Sep 2020 16:43:32
User entered 'None (1)'	System	02 Sep 2020 16:43:32

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:16', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9fdb8ebd-4239-43ab-96bd-00235ada31dc'	System	02 Sep 2020 16:43:32
User entered 'No (N)'	System	02 Sep 2020 16:43:32

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:19', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9fdb8ebd-4239-43ab-96bd-00235ada31dc'	System	02 Sep 2020 16:43:32
User entered 'No (N)'	System	02 Sep 2020 16:43:32

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:22', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9fdb8ebd-4239-43ab-96bd-00235ada31dc'	System	02 Sep 2020 16:43:32
User entered 'None (1)'	System	02 Sep 2020 16:43:32

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:28', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9fdb8ebd-4239-43ab-96bd-00235ada31dc'	System	02 Sep 2020 16:43:32
User entered '02 Sep 2020 12:43'	System	02 Sep 2020 16:43:32

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 7'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:16:57', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b7dd8ced-638f-4f3c-bc88-c57fba6f4f28'	System	03 Sep 2020 16:17:12
User entered 'None (1)'	System	03 Sep 2020 16:17:12

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:17:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b7dd8ced-638f-4f3c-bc88-c57fba6f4f28'	System	03 Sep 2020 16:17:12
User entered 'No (N)'	System	03 Sep 2020 16:17:12

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:17:02', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b7dd8ced-638f-4f3c-bc88-c57fba6f4f28'	System	03 Sep 2020 16:17:12
User entered 'No (N)'	System	03 Sep 2020 16:17:12

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:17:05', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b7dd8ced-638f-4f3c-bc88-c57fba6f4f28'	System	03 Sep 2020 16:17:12
User entered 'None (1)'	System	03 Sep 2020 16:17:12

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:17:08', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b7dd8ced-638f-4f3c-bc88-c57fba6f4f28'	System	03 Sep 2020 16:17:12
User entered '03 Sep 2020 12:17'	System	03 Sep 2020 16:17:12

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:55:23', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '065d4e59-a9b7-4453-a299-42ed2254ecc6'	System	28 Aug 2020 18:55:50
User entered 'None (0)'	System	28 Aug 2020 18:55:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:55:26', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '065d4e59-a9b7-4453-a299-42ed2254ecc6'	System	28 Aug 2020 18:55:50
User entered 'None (0)'	System	28 Aug 2020 18:55:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:55:29', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '065d4e59-a9b7-4453-a299-42ed2254ecc6'	System	28 Aug 2020 18:55:50
User entered 'None (0)'	System	28 Aug 2020 18:55:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:55:32', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '065d4e59-a9b7-4453-a299-42ed2254ecc6'	System	28 Aug 2020 18:55:50
User entered 'None (0)'	System	28 Aug 2020 18:55:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:55:34', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '065d4e59-a9b7-4453-a299-42ed2254ecc6'	System	28 Aug 2020 18:55:50
User entered 'None (0)'	System	28 Aug 2020 18:55:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:55:37', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '065d4e59-a9b7-4453-a299-42ed2254ecc6'	System	28 Aug 2020 18:55:50
User entered 'None (0)'	System	28 Aug 2020 18:55:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:55:42', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '065d4e59-a9b7-4453-a299-42ed2254ecc6'	System	28 Aug 2020 18:55:50
User entered 'No (N)'	System	28 Aug 2020 18:55:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T14:55:47', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '065d4e59-a9b7-4453-a299-42ed2254ecc6'	System	28 Aug 2020 18:55:50
User entered '28 Aug 2020 14:55'	System	28 Aug 2020 18:55:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '28 Aug 2020 14:53'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '28 Aug 2020 17:23'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:19:16', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2ff4e3a8-9060-4e58-9dbd-0d05ab7beddf'	System	28 Aug 2020 22:19:44
User entered 'None (0)'	System	28 Aug 2020 22:19:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:19:19', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2ff4e3a8-9060-4e58-9dbd-0d05ab7beddf'	System	28 Aug 2020 22:19:44
User entered 'None (0)'	System	28 Aug 2020 22:19:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:19:22', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2ff4e3a8-9060-4e58-9dbd-0d05ab7beddf'	System	28 Aug 2020 22:19:44
User entered 'None (0)'	System	28 Aug 2020 22:19:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:19:25', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2ff4e3a8-9060-4e58-9dbd-0d05ab7beddf'	System	28 Aug 2020 22:19:44
User entered 'None (0)'	System	28 Aug 2020 22:19:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:19:28', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2ff4e3a8-9060-4e58-9dbd-0d05ab7beddf'	System	28 Aug 2020 22:19:44
User entered 'None (0)'	System	28 Aug 2020 22:19:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:19:31', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2ff4e3a8-9060-4e58-9dbd-0d05ab7beddf'	System	28 Aug 2020 22:19:44
User entered 'None (0)'	System	28 Aug 2020 22:19:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:19:36', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2ff4e3a8-9060-4e58-9dbd-0d05ab7beddf'	System	28 Aug 2020 22:19:44
User entered 'No (N)'	System	28 Aug 2020 22:19:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-28T18:19:40', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2ff4e3a8-9060-4e58-9dbd-0d05ab7beddf'	System	28 Aug 2020 22:19:44
User entered '28 Aug 2020 18:19'	System	28 Aug 2020 22:19:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '28 Aug 2020 18:18'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 2'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:14:21', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c4a59aa3-229d-4c28-b61d-f115494b7909'	System	30 Aug 2020 16:02:46
User entered 'None (0)'	System	30 Aug 2020 16:02:46

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:14:25', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c4a59aa3-229d-4c28-b61d-f115494b7909'	System	30 Aug 2020 16:02:46
User entered 'None (0)'	System	30 Aug 2020 16:02:46

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:14:28', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c4a59aa3-229d-4c28-b61d-f115494b7909'	System	30 Aug 2020 16:02:46
User entered 'None (0)'	System	30 Aug 2020 16:02:46

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:14:31', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c4a59aa3-229d-4c28-b61d-f115494b7909'	System	30 Aug 2020 16:02:46
User entered 'None (0)'	System	30 Aug 2020 16:02:46

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:14:34', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c4a59aa3-229d-4c28-b61d-f115494b7909'	System	30 Aug 2020 16:02:46
User entered 'None (0)'	System	30 Aug 2020 16:02:46

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:14:37', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c4a59aa3-229d-4c28-b61d-f115494b7909'	System	30 Aug 2020 16:02:46
User entered 'None (0)'	System	30 Aug 2020 16:02:46

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

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)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:14:41', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c4a59aa3-229d-4c28-b61d-f115494b7909'	System	30 Aug 2020 16:02:46
User entered 'No (N)'	System	30 Aug 2020 16:02:46

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-29T12:14:45', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c4a59aa3-229d-4c28-b61d-f115494b7909'	System	30 Aug 2020 16:02:46
User entered '29 Aug 2020 12:14'	System	30 Aug 2020 16:02:46

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 3'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:03:33', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '0a7fc13f-3cfc-41a7-90d3-c666f84adf41'	System	30 Aug 2020 16:04:09
User entered 'None (0)'	System	30 Aug 2020 16:04:09

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:03:37', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '0a7fc13f-3cfc-41a7-90d3-c666f84adf41'	System	30 Aug 2020 16:04:09
User entered 'None (0)'	System	30 Aug 2020 16:04:09

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:03:42', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '0a7fc13f-3cfc-41a7-90d3-c666f84adf41'	System	30 Aug 2020 16:04:09
User entered 'None (0)'	System	30 Aug 2020 16:04:09

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:03:47', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '0a7fc13f-3cfc-41a7-90d3-c666f84adf41'	System	30 Aug 2020 16:04:09
User entered 'None (0)'	System	30 Aug 2020 16:04:09

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:03:50', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '0a7fc13f-3cfc-41a7-90d3-c666f84adf41'	System	30 Aug 2020 16:04:09
User entered 'None (0)'	System	30 Aug 2020 16:04:09

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:03:53', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '0a7fc13f-3cfc-41a7-90d3-c666f84adf41'	System	30 Aug 2020 16:04:09
User entered 'None (0)'	System	30 Aug 2020 16:04:09

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

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)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:04:01', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '0a7fc13f-3cfc-41a7-90d3-c666f84adf41'	System	30 Aug 2020 16:04:09
User entered 'No (N)'	System	30 Aug 2020 16:04:09

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-30T12:04:05', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '0a7fc13f-3cfc-41a7-90d3-c666f84adf41'	System	30 Aug 2020 16:04:09
User entered '30 Aug 2020 12:04'	System	30 Aug 2020 16:04:09

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 4'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:15:04', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'eee9fea1-2001-47e5-ad26-5c7b6227d6c7'	System	31 Aug 2020 16:24:50
User entered 'None (0)'	System	31 Aug 2020 16:24:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:15:08', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'eee9fea1-2001-47e5-ad26-5c7b6227d6c7'	System	31 Aug 2020 16:24:50
User entered 'None (0)'	System	31 Aug 2020 16:24:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:15:11', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'eee9fea1-2001-47e5-ad26-5c7b6227d6c7'	System	31 Aug 2020 16:24:50
User entered 'None (0)'	System	31 Aug 2020 16:24:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:15:15', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'eee9fea1-2001-47e5-ad26-5c7b6227d6c7'	System	31 Aug 2020 16:24:50
User entered 'None (0)'	System	31 Aug 2020 16:24:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:15:18', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'eee9fea1-2001-47e5-ad26-5c7b6227d6c7'	System	31 Aug 2020 16:24:50
User entered 'None (0)'	System	31 Aug 2020 16:24:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:15:21', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'eee9fea1-2001-47e5-ad26-5c7b6227d6c7'	System	31 Aug 2020 16:24:50
User entered 'None (0)'	System	31 Aug 2020 16:24:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

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)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:15:24', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'eee9fea1-2001-47e5-ad26-5c7b6227d6c7'	System	31 Aug 2020 16:24:50
User entered 'No (N)'	System	31 Aug 2020 16:24:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-08-31T12:15:30', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'eee9fea1-2001-47e5-ad26-5c7b6227d6c7'	System	31 Aug 2020 16:24:50
User entered '31 Aug 2020 12:15'	System	31 Aug 2020 16:24:50

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 5'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:05:33', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b1ba17f4-4ee2-4447-9c5a-24a3823439e2'	System	01 Sep 2020 16:06:10
User entered 'None (0)'	System	01 Sep 2020 16:06:10

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:05:37', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b1ba17f4-4ee2-4447-9c5a-24a3823439e2'	System	01 Sep 2020 16:06:10
User entered 'None (0)'	System	01 Sep 2020 16:06:10

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:05:40', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b1ba17f4-4ee2-4447-9c5a-24a3823439e2'	System	01 Sep 2020 16:06:10
User entered 'None (0)'	System	01 Sep 2020 16:06:10

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:05:43', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b1ba17f4-4ee2-4447-9c5a-24a3823439e2'	System	01 Sep 2020 16:06:10
User entered 'None (0)'	System	01 Sep 2020 16:06:10

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:05:46', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b1ba17f4-4ee2-4447-9c5a-24a3823439e2'	System	01 Sep 2020 16:06:10
User entered 'None (0)'	System	01 Sep 2020 16:06:10

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:05:49', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b1ba17f4-4ee2-4447-9c5a-24a3823439e2'	System	01 Sep 2020 16:06:10
User entered 'None (0)'	System	01 Sep 2020 16:06:10

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

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)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:05:54', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b1ba17f4-4ee2-4447-9c5a-24a3823439e2'	System	01 Sep 2020 16:06:10
User entered 'No (N)'	System	01 Sep 2020 16:06:10

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-01T12:06:03', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b1ba17f4-4ee2-4447-9c5a-24a3823439e2'	System	01 Sep 2020 16:06:10
User entered '01 Sep 2020 12:06'	System	01 Sep 2020 16:06:10

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 6'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:35', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a04ece12-46c9-4f79-aab4-9fd822f1d7c7'	System	02 Sep 2020 16:44:14
User entered 'None (0)'	System	02 Sep 2020 16:44:14

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:38', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a04ece12-46c9-4f79-aab4-9fd822f1d7c7'	System	02 Sep 2020 16:44:14
User entered 'None (0)'	System	02 Sep 2020 16:44:14

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:42', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a04ece12-46c9-4f79-aab4-9fd822f1d7c7'	System	02 Sep 2020 16:44:14
User entered 'None (0)'	System	02 Sep 2020 16:44:14

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:45', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a04ece12-46c9-4f79-aab4-9fd822f1d7c7'	System	02 Sep 2020 16:44:14
User entered 'None (0)'	System	02 Sep 2020 16:44:14

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:50', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a04ece12-46c9-4f79-aab4-9fd822f1d7c7'	System	02 Sep 2020 16:44:14
User entered 'None (0)'	System	02 Sep 2020 16:44:14

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:54', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a04ece12-46c9-4f79-aab4-9fd822f1d7c7'	System	02 Sep 2020 16:44:14
User entered 'None (0)'	System	02 Sep 2020 16:44:14

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

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)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:43:58', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a04ece12-46c9-4f79-aab4-9fd822f1d7c7'	System	02 Sep 2020 16:44:14
User entered 'No (N)'	System	02 Sep 2020 16:44:14

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-02T12:44:10', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a04ece12-46c9-4f79-aab4-9fd822f1d7c7'	System	02 Sep 2020 16:44:14
User entered '02 Sep 2020 12:44'	System	02 Sep 2020 16:44:14

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 7'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:17:14', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '186b1858-7dae-4da7-9fe3-5a5a92640771'	System	03 Sep 2020 16:17:39
User entered 'None (0)'	System	03 Sep 2020 16:17:39

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:17:17', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '186b1858-7dae-4da7-9fe3-5a5a92640771'	System	03 Sep 2020 16:17:39
User entered 'None (0)'	System	03 Sep 2020 16:17:39

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:17:20', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '186b1858-7dae-4da7-9fe3-5a5a92640771'	System	03 Sep 2020 16:17:39
User entered 'None (0)'	System	03 Sep 2020 16:17:39

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:17:22', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '186b1858-7dae-4da7-9fe3-5a5a92640771'	System	03 Sep 2020 16:17:39
User entered 'None (0)'	System	03 Sep 2020 16:17:39

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:17:25', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '186b1858-7dae-4da7-9fe3-5a5a92640771'	System	03 Sep 2020 16:17:39
User entered 'None (0)'	System	03 Sep 2020 16:17:39

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:17:28', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '186b1858-7dae-4da7-9fe3-5a5a92640771'	System	03 Sep 2020 16:17:39
User entered 'None (0)'	System	03 Sep 2020 16:17:39

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

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)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:17:31', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '186b1858-7dae-4da7-9fe3-5a5a92640771'	System	03 Sep 2020 16:17:39
User entered 'No (N)'	System	03 Sep 2020 16:17:39

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-03T12:17:34', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '186b1858-7dae-4da7-9fe3-5a5a92640771'	System	03 Sep 2020 16:17:39
User entered '03 Sep 2020 12:17'	System	03 Sep 2020 16:17:39

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 18:43:44

US3202304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:43
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:27:09
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	21 Oct 2020 13:52:02

US3202304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:27:09
User entered '4 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	21 Oct 2020 13:52:02

US3202304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:27:09
User entered 'Contact Not Made (CONTACT NOT MADE)'	Tiffany Jewell (b) (4) (b) (4)	21 Oct 2020 13:52:02

US3202304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:27:09
User entered 'LVM'	Tiffany Jewell (b) (4) (b) (4)	21 Oct 2020 13:52:02

US3202304

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:28:57
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 13:55:27

US3202304

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'I'	System	25 Sep 2020 13:55:27

US3202304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:29:06
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	21 Oct 2020 13:52:39

US3202304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:29:06
User entered '11 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	21 Oct 2020 13:52:39

US3202304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:29:06
User entered 'Contact Not Made (CONTACT NOT MADE)'	Tiffany Jewell (b) (4) (b) (4)	21 Oct 2020 13:52:39

US3202304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:29:06
User entered 'LVM'	Tiffany Jewell (b) (4) (b) (4)	21 Oct 2020 13:52:39

US3202304

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:29:42
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 13:57:36

US3202304

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'I'	System	25 Sep 2020 13:57:36

US3202304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:30:39
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	21 Oct 2020 13:53:38

US3202304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:30:39
User entered '18 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	21 Oct 2020 13:53:38

US3202304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:30:39
User entered 'Contact Made (CONTACT MADE)'	Tiffany Jewell (b) (4) (b) (4)	21 Oct 2020 13:53:38

US3202304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:30:39
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	21 Oct 2020 13:53:38

US3202304

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:30:44
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 13:57:42

US3202304

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'I'	System	25 Sep 2020 13:57:42

US3202304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:56:28
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 13:57:53

US3202304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:56:28
User entered '25 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 13:57:53

US3202304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[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 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:56:28
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 13:57:53

US3202304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'VISIT2'	System	25 Sep 2020 13:57:53

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '25 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '09:16'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '25 Sep 2020 09:16'	System	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '37.2' C	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered 'Oral (Oral)'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '83'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'bpm'	System	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '18'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'breaths/min'	System	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '140'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'mmHg'	System	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '91'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'mmHg'	System	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '25 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '10:37'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '25 Sep 2020 10:37'	System	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '36.7' C	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered 'Oral (Oral)'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '86'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'bpm'	System	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '20'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'breaths/min'	System	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '146'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'mmHg'	System	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:06
User entered '89'	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'mmHg'	System	28 Sep 2020 14:46:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:44
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 13:58:02

US3202304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:57:44
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 13:58:02

US3202304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:01
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:21:22

US3202304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:01
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:21:22

US3202304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

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 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:01
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:21:22

US3202304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 14:21:22

US3202304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:01
User entered '25 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:21:22

US3202304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:01
User entered '10:00'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:21:22

US3202304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '25 Sep 2020 10:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:01
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:21:22

US3202304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:58:01
User entered 'ONCE'	System	25 Sep 2020 14:21:22

US3202304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 14:21:22

US3202304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:39
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:27:09

US3202304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:39
User entered '25 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:27:09

US3202304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:39
User entered '09:26'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:27:09

US3202304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '25 Sep 2020 09:26'	System	25 Sep 2020 14:27:09

US3202304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:48
User entered '25 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:27:19

US3202304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	25 Sep 2020 14:27:19

US3202304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:48
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:27:19

US3202304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:48
User entered '09:24'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:27:19

US3202304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '25 Sep 2020 09:24'	System	25 Sep 2020 14:27:19

US3202304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	25 Sep 2020 14:27:19

US3202304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:48
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:27:19

US3202304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:58:48
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:27:19

US3202304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered empty.	System	25 Sep 2020 14:27:19

US3202304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:59:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	25 Sep 2020 14:00:50

US3202304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '1'	System	25 Sep 2020 14:00:50

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:33:42', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '09fa1119-0262-4c15-af7d-e817f8878d6d'	System	25 Sep 2020 14:34:15
User entered 'Yes (Y)'	System	25 Sep 2020 14:34:15

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:33:59', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '09fa1119-0262-4c15-af7d-e817f8878d6d'	System	25 Sep 2020 14:34:15
User entered '98.1'	System	25 Sep 2020 14:34:15

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:34:05', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '09fa1119-0262-4c15-af7d-e817f8878d6d'	System	25 Sep 2020 14:34:15
User entered 'No (N)'	System	25 Sep 2020 14:34:15

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:34:12', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '09fa1119-0262-4c15-af7d-e817f8878d6d'	System	25 Sep 2020 14:34:15
User entered '25 Sep 2020 10:34'	System	25 Sep 2020 14:34:15

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '25 Sep 2020 10:20'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '25 Sep 2020 12:50'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:26:30', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c2bae429-98b0-4d12-97ae-115e22591f79'	System	25 Sep 2020 18:26:50
User entered 'Yes (Y)'	System	25 Sep 2020 18:26:50

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:26:38', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c2bae429-98b0-4d12-97ae-115e22591f79'	System	25 Sep 2020 18:26:50
User entered '98.0'	System	25 Sep 2020 18:26:50

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:26:42', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c2bae429-98b0-4d12-97ae-115e22591f79'	System	25 Sep 2020 18:26:50
User entered 'No (N)'	System	25 Sep 2020 18:26:50

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:26:47', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c2bae429-98b0-4d12-97ae-115e22591f79'	System	25 Sep 2020 18:26:50
User entered '25 Sep 2020 14:26'	System	25 Sep 2020 18:26:50

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '25 Sep 2020 13:45'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 2'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:08', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '06618056-f4ef-4c96-a487-8ef6e8069ab7'	System	26 Sep 2020 19:35:27
User entered 'Yes (Y)'	System	26 Sep 2020 19:35:27

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:15', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '06618056-f4ef-4c96-a487-8ef6e8069ab7'	System	26 Sep 2020 19:35:27
User entered '98.4'	System	26 Sep 2020 19:35:27

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:19', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '06618056-f4ef-4c96-a487-8ef6e8069ab7'	System	26 Sep 2020 19:35:27
User entered 'No (N)'	System	26 Sep 2020 19:35:27

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:23', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '06618056-f4ef-4c96-a487-8ef6e8069ab7'	System	26 Sep 2020 19:35:27
User entered '26 Sep 2020 15:35'	System	26 Sep 2020 19:35:27

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 3'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:01', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6606990a-1afd-499f-86b2-5460c4a6bed1'	System	27 Sep 2020 16:08:20
User entered 'Yes (Y)'	System	27 Sep 2020 16:08:20

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:07', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6606990a-1afd-499f-86b2-5460c4a6bed1'	System	27 Sep 2020 16:08:20
User entered '99.6'	System	27 Sep 2020 16:08:20

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:10', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6606990a-1afd-499f-86b2-5460c4a6bed1'	System	27 Sep 2020 16:08:20
User entered 'No (N)'	System	27 Sep 2020 16:08:20

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:17', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6606990a-1afd-499f-86b2-5460c4a6bed1' User entered '27 Sep 2020 12:08'	System	27 Sep 2020 16:08:20
	System	27 Sep 2020 16:08:20

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 4'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:04:05', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b1aede73-e84b-46b0-bdee-4fbac73007d1'	System	28 Sep 2020 16:06:11
User entered 'Yes (Y)'	System	28 Sep 2020 16:06:11

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:05:58', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b1aede73-e84b-46b0-bdee-4fbac73007d1'	System	28 Sep 2020 16:06:11
User entered '96.7'	System	28 Sep 2020 16:06:11

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:01', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b1aede73-e84b-46b0-bdee-4fbac73007d1'	System	28 Sep 2020 16:06:11
User entered 'No (N)'	System	28 Sep 2020 16:06:11

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:05', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'b1aede73-e84b-46b0-bdee-4fbac73007d1'	System	28 Sep 2020 16:06:11
User entered '28 Sep 2020 12:06'	System	28 Sep 2020 16:06:11

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 5'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:20:59', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '3922b615-b150-46c4-9fe0-f2d94d8cb1c0'	System	29 Sep 2020 16:21:38
User entered 'Yes (Y)'	System	29 Sep 2020 16:21:38

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:05', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '3922b615-b150-46c4-9fe0-f2d94d8cb1c0'	System	29 Sep 2020 16:21:38
User entered '98.1'	System	29 Sep 2020 16:21:38

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:09', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '3922b615-b150-46c4-9fe0-f2d94d8cb1c0'	System	29 Sep 2020 16:21:38
User entered 'No (N)'	System	29 Sep 2020 16:21:38

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:13', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '3922b615-b150-46c4-9fe0-f2d94d8cb1c0'	System	29 Sep 2020 16:21:38
User entered '29 Sep 2020 12:21'	System	29 Sep 2020 16:21:38

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 6'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:19:19', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '155dae20-8801-418d-9ae7-2c899d01fa40'	System	30 Sep 2020 16:19:36
User entered 'Yes (Y)'	System	30 Sep 2020 16:19:36

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:19:26', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '155dae20-8801-418d-9ae7-2c899d01fa40'	System	30 Sep 2020 16:19:36
User entered '98.8'	System	30 Sep 2020 16:19:36

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:19:30', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '155dae20-8801-418d-9ae7-2c899d01fa40'	System	30 Sep 2020 16:19:36
User entered 'No (N)'	System	30 Sep 2020 16:19:36

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:19:33', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '155dae20-8801-418d-9ae7-2c899d01fa40'	System	30 Sep 2020 16:19:36
User entered '30 Sep 2020 12:19'	System	30 Sep 2020 16:19:36

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 7'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:01:42', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2f7c07e9-79b8-4cc2-a53b-b7cf28851288'	System	01 Oct 2020 16:02:19
User entered 'Yes (Y)'	System	01 Oct 2020 16:02:19

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:01:49', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2f7c07e9-79b8-4cc2-a53b-b7cf28851288'	System	01 Oct 2020 16:02:19
User entered '97.8'	System	01 Oct 2020 16:02:19

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:01:54', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2f7c07e9-79b8-4cc2-a53b-b7cf28851288'	System	01 Oct 2020 16:02:19
User entered 'No (N)'	System	01 Oct 2020 16:02:19

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:01:58', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2f7c07e9-79b8-4cc2-a53b-b7cf28851288'	System	01 Oct 2020 16:02:19
User entered '01 Oct 2020 12:01'	System	01 Oct 2020 16:02:19

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:05', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '1f4d8798-5ed0-49ef-9523-f4ef73006fcb'	System	25 Sep 2020 14:35:21
User entered 'None (1)'	System	25 Sep 2020 14:35:21

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:08', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '1f4d8798-5ed0-49ef-9523-f4ef73006fcb'	System	25 Sep 2020 14:35:21
User entered 'No (N)'	System	25 Sep 2020 14:35:21

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:11', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '1f4d8798-5ed0-49ef-9523-f4ef73006fcb'	System	25 Sep 2020 14:35:21
User entered 'No (N)'	System	25 Sep 2020 14:35:21

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:14', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '1f4d8798-5ed0-49ef-9523-f4ef73006fcb'	System	25 Sep 2020 14:35:21
User entered 'None (1)'	System	25 Sep 2020 14:35:21

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:17', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '1f4d8798-5ed0-49ef-9523-f4ef73006fcb'	System	25 Sep 2020 14:35:21
User entered '25 Sep 2020 10:35'	System	25 Sep 2020 14:35:21

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '25 Sep 2020 10:20'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '25 Sep 2020 12:50'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:27:02', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '906fa009-8ade-43fe-9f07-2b4394b39b95'	System	25 Sep 2020 18:27:42
User entered 'None (1)'	System	25 Sep 2020 18:27:42

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:27:25', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '906fa009-8ade-43fe-9f07-2b4394b39b95'	System	25 Sep 2020 18:27:42
User entered 'No (N)'	System	25 Sep 2020 18:27:42

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:27:29', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '906fa009-8ade-43fe-9f07-2b4394b39b95'	System	25 Sep 2020 18:27:42
User entered 'No (N)'	System	25 Sep 2020 18:27:42

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:27:34', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '906fa009-8ade-43fe-9f07-2b4394b39b95'	System	25 Sep 2020 18:27:42
User entered 'None (1)'	System	25 Sep 2020 18:27:42

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:27:38', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '906fa009-8ade-43fe-9f07-2b4394b39b95'	System	25 Sep 2020 18:27:42
User entered '25 Sep 2020 14:27'	System	25 Sep 2020 18:27:42

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '25 Sep 2020 13:45'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 2'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:28', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '83d63473-9adb-405e-a529-92bc93a4595b'	System	26 Sep 2020 19:35:42
User entered 'None (1)'	System	26 Sep 2020 19:35:42

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:31', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '83d63473-9adb-405e-a529-92bc93a4595b'	System	26 Sep 2020 19:35:42
User entered 'No (N)'	System	26 Sep 2020 19:35:42

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:34', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '83d63473-9adb-405e-a529-92bc93a4595b'	System	26 Sep 2020 19:35:42
User entered 'No (N)'	System	26 Sep 2020 19:35:42

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:37', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '83d63473-9adb-405e-a529-92bc93a4595b'	System	26 Sep 2020 19:35:42
User entered 'None (1)'	System	26 Sep 2020 19:35:42

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:39', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '83d63473-9adb-405e-a529-92bc93a4595b'	System	26 Sep 2020 19:35:42
User entered '26 Sep 2020 15:35'	System	26 Sep 2020 19:35:42

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 3'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:22', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2be85ef0-e2a3-4396-a8f9-41e40a89f6d3'	System	27 Sep 2020 16:08:38
User entered 'None (1)'	System	27 Sep 2020 16:08:38

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:25', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2be85ef0-e2a3-4396-a8f9-41e40a89f6d3'	System	27 Sep 2020 16:08:38
User entered 'No (N)'	System	27 Sep 2020 16:08:38

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:28', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2be85ef0-e2a3-4396-a8f9-41e40a89f6d3'	System	27 Sep 2020 16:08:38
User entered 'No (N)'	System	27 Sep 2020 16:08:38

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:32', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2be85ef0-e2a3-4396-a8f9-41e40a89f6d3'	System	27 Sep 2020 16:08:38
User entered 'None (1)'	System	27 Sep 2020 16:08:38

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:35', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '2be85ef0-e2a3-4396-a8f9-41e40a89f6d3'	System	27 Sep 2020 16:08:38
User entered '27 Sep 2020 12:08'	System	27 Sep 2020 16:08:38

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 4'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:13', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'bf082920-0b68-4ca9-8d4c-1920f9a8f2b8'	System	28 Sep 2020 16:06:29
User entered 'None (1)'	System	28 Sep 2020 16:06:29

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:16', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'bf082920-0b68-4ca9-8d4c-1920f9a8f2b8'	System	28 Sep 2020 16:06:29
User entered 'No (N)'	System	28 Sep 2020 16:06:29

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:19', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'bf082920-0b68-4ca9-8d4c-1920f9a8f2b8'	System	28 Sep 2020 16:06:29
User entered 'No (N)'	System	28 Sep 2020 16:06:29

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:23', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'bf082920-0b68-4ca9-8d4c-1920f9a8f2b8'	System	28 Sep 2020 16:06:29
User entered 'None (1)'	System	28 Sep 2020 16:06:29

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:26', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'bf082920-0b68-4ca9-8d4c-1920f9a8f2b8'	System	28 Sep 2020 16:06:29
User entered '28 Sep 2020 12:06'	System	28 Sep 2020 16:06:29

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 5'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:18', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c0617e5a-8096-4d10-a1aa-db1a90a5eb67'	System	29 Sep 2020 16:21:43
User entered 'None (1)'	System	29 Sep 2020 16:21:43

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:21', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c0617e5a-8096-4d10-a1aa-db1a90a5eb67'	System	29 Sep 2020 16:21:43
User entered 'No (N)'	System	29 Sep 2020 16:21:43

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:24', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c0617e5a-8096-4d10-a1aa-db1a90a5eb67'	System	29 Sep 2020 16:21:43
User entered 'No (N)'	System	29 Sep 2020 16:21:43

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:27', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c0617e5a-8096-4d10-a1aa-db1a90a5eb67'	System	29 Sep 2020 16:21:43
User entered 'None (1)'	System	29 Sep 2020 16:21:43

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:30', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c0617e5a-8096-4d10-a1aa-db1a90a5eb67'	System	29 Sep 2020 16:21:43
User entered '29 Sep 2020 12:21'	System	29 Sep 2020 16:21:43

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 6'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:19:39', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c1ff4ab9-07b9-4600-876e-cfbae0fb0e12'	System	30 Sep 2020 16:19:55
User entered 'None (1)'	System	30 Sep 2020 16:19:55

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:19:43', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c1ff4ab9-07b9-4600-876e-cfbae0fb0e12'	System	30 Sep 2020 16:19:55
User entered 'No (N)'	System	30 Sep 2020 16:19:55

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:19:46', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c1ff4ab9-07b9-4600-876e-cfbae0fb0e12'	System	30 Sep 2020 16:19:55
User entered 'No (N)'	System	30 Sep 2020 16:19:55

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:19:49', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c1ff4ab9-07b9-4600-876e-cfbae0fb0e12'	System	30 Sep 2020 16:19:55
User entered 'None (1)'	System	30 Sep 2020 16:19:55

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:19:53', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'c1ff4ab9-07b9-4600-876e-cfb0e12'	System	30 Sep 2020 16:19:55
User entered '30 Sep 2020 12:19'	System	30 Sep 2020 16:19:55

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 7'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:04', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f270589f-4827-43a6-8cea-a567f3a22028'	System	01 Oct 2020 16:02:27
User entered 'None (1)'	System	01 Oct 2020 16:02:27

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:07', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f270589f-4827-43a6-8cea-a567f3a22028'	System	01 Oct 2020 16:02:27
User entered 'No (N)'	System	01 Oct 2020 16:02:27

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:09', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f270589f-4827-43a6-8cea-a567f3a22028'	System	01 Oct 2020 16:02:27
User entered 'No (N)'	System	01 Oct 2020 16:02:27

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:12', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f270589f-4827-43a6-8cea-a567f3a22028'	System	01 Oct 2020 16:02:27
User entered 'None (1)'	System	01 Oct 2020 16:02:27

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:16', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f270589f-4827-43a6-8cea-a567f3a22028'	System	01 Oct 2020 16:02:27
User entered '01 Oct 2020 12:02'	System	01 Oct 2020 16:02:27

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:23', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f1bff737-ebde-499c-a4b3-977f3e65b2c9'	System	25 Sep 2020 14:35:52
User entered 'None (0)'	System	25 Sep 2020 14:35:52

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:27', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f1bff737-ebde-499c-a4b3-977f3e65b2c9'	System	25 Sep 2020 14:35:52
User entered 'None (0)'	System	25 Sep 2020 14:35:52

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:30', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f1bff737-ebde-499c-a4b3-977f3e65b2c9'	System	25 Sep 2020 14:35:52
User entered 'None (0)'	System	25 Sep 2020 14:35:52

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:34', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f1bff737-ebde-499c-a4b3-977f3e65b2c9'	System	25 Sep 2020 14:35:52
User entered 'None (0)'	System	25 Sep 2020 14:35:52

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:38', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f1bff737-ebde-499c-a4b3-977f3e65b2c9' User entered 'None (0)'	System	25 Sep 2020 14:35:52
	System	25 Sep 2020 14:35:52

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:42', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f1bff737-ebde-499c-a4b3-977f3e65b2c9'	System	25 Sep 2020 14:35:52
User entered 'None (0)'	System	25 Sep 2020 14:35:52

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

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)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:45', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f1bff737-ebde-499c-a4b3-977f3e65b2c9'	System	25 Sep 2020 14:35:52
User entered 'No (N)'	System	25 Sep 2020 14:35:52

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T10:35:48', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f1bff737-ebde-499c-a4b3-977f3e65b2c9'	System	25 Sep 2020 14:35:52
User entered '25 Sep 2020 10:35'	System	25 Sep 2020 14:35:52

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '25 Sep 2020 10:20'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '25 Sep 2020 12:50'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:27:44', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'abcb3575-7620-463f-b08a-12491d610b07'	System	25 Sep 2020 18:28:24
User entered 'None (0)'	System	25 Sep 2020 18:28:24

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:27:48', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'abcb3575-7620-463f-b08a-12491d610b07'	System	25 Sep 2020 18:28:24
User entered 'None (0)'	System	25 Sep 2020 18:28:24

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:27:54', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'abcb3575-7620-463f-b08a-12491d610b07'	System	25 Sep 2020 18:28:24
User entered 'None (0)'	System	25 Sep 2020 18:28:24

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:28:07', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'abcb3575-7620-463f-b08a-12491d610b07'	System	25 Sep 2020 18:28:24
User entered 'None (0)'	System	25 Sep 2020 18:28:24

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:28:10', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'abcb3575-7620-463f-b08a-12491d610b07'	System	25 Sep 2020 18:28:24
User entered 'None (0)'	System	25 Sep 2020 18:28:24

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:28:14', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'abcb3575-7620-463f-b08a-12491d610b07'	System	25 Sep 2020 18:28:24
User entered 'None (0)'	System	25 Sep 2020 18:28:24

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

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)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:28:18', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'abcb3575-7620-463f-b08a-12491d610b07'	System	25 Sep 2020 18:28:24
User entered 'No (N)'	System	25 Sep 2020 18:28:24

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-25T14:28:21', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'abcb3575-7620-463f-b08a-12491d610b07'	System	25 Sep 2020 18:28:24
User entered '25 Sep 2020 14:28'	System	25 Sep 2020 18:28:24

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '25 Sep 2020 13:45'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 2'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:45', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '82131815-45c9-4983-843a-92f26bb0fa4b'	System	26 Sep 2020 19:36:09
User entered 'None (0)'	System	26 Sep 2020 19:36:09

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:49', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '82131815-45c9-4983-843a-92f26bb0fa4b'	System	26 Sep 2020 19:36:09
User entered 'None (0)'	System	26 Sep 2020 19:36:09

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:52', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '82131815-45c9-4983-843a-92f26bb0fa4b'	System	26 Sep 2020 19:36:09
User entered 'None (0)'	System	26 Sep 2020 19:36:09

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:55', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '82131815-45c9-4983-843a-92f26bb0fa4b'	System	26 Sep 2020 19:36:09
User entered 'None (0)'	System	26 Sep 2020 19:36:09

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:35:57', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '82131815-45c9-4983-843a-92f26bb0fa4b'	System	26 Sep 2020 19:36:09
User entered 'None (0)'	System	26 Sep 2020 19:36:09

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:36:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '82131815-45c9-4983-843a-92f26bb0fa4b'	System	26 Sep 2020 19:36:09
User entered 'None (0)'	System	26 Sep 2020 19:36:09

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

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)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:36:03', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '82131815-45c9-4983-843a-92f26bb0fa4b'	System	26 Sep 2020 19:36:09
User entered 'No (N)'	System	26 Sep 2020 19:36:09

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-26T15:36:05', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '82131815-45c9-4983-843a-92f26bb0fa4b'	System	26 Sep 2020 19:36:09
User entered '26 Sep 2020 15:36'	System	26 Sep 2020 19:36:09

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 3'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:40', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4012b9f4-7bd1-484f-bcee-3c6a5cf8fc5d'	System	27 Sep 2020 16:09:05
User entered 'None (0)'	System	27 Sep 2020 16:09:05

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:43', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4012b9f4-7bd1-484f-bcee-3c6a5cf8fc5d'	System	27 Sep 2020 16:09:05
User entered 'None (0)'	System	27 Sep 2020 16:09:05

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:46', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4012b9f4-7bd1-484f-bcee-3c6a5cf8fc5d'	System	27 Sep 2020 16:09:05
User entered 'None (0)'	System	27 Sep 2020 16:09:05

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:49', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4012b9f4-7bd1-484f-bcee-3c6a5cf8fc5d'	System	27 Sep 2020 16:09:05
User entered 'None (0)'	System	27 Sep 2020 16:09:05

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:51', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4012b9f4-7bd1-484f-bcee-3c6a5cf8fc5d'	System	27 Sep 2020 16:09:05
User entered 'None (0)'	System	27 Sep 2020 16:09:05

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:54', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4012b9f4-7bd1-484f-bcee-3c6a5cf8fc5d'	System	27 Sep 2020 16:09:05
User entered 'None (0)'	System	27 Sep 2020 16:09:05

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

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)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:08:57', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4012b9f4-7bd1-484f-bcee-3c6a5cf8fc5d'	System	27 Sep 2020 16:09:05
User entered 'No (N)'	System	27 Sep 2020 16:09:05

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-27T12:09:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4012b9f4-7bd1-484f-bcee-3c6a5cf8fc5d'	System	27 Sep 2020 16:09:05
User entered '27 Sep 2020 12:09'	System	27 Sep 2020 16:09:05

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 4'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:32', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '803d0d4d-369f-46ee-bb3b-6e7c7ef753f3'	System	28 Sep 2020 16:07:06
User entered 'None (0)'	System	28 Sep 2020 16:07:06

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:36', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '803d0d4d-369f-46ee-bb3b-6e7c7ef753f3'	System	28 Sep 2020 16:07:06
User entered 'None (0)'	System	28 Sep 2020 16:07:06

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:39', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '803d0d4d-369f-46ee-bb3b-6e7c7ef753f3'	System	28 Sep 2020 16:07:06
User entered 'None (0)'	System	28 Sep 2020 16:07:06

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:42', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '803d0d4d-369f-46ee-bb3b-6e7c7ef753f3'	System	28 Sep 2020 16:07:06
User entered 'None (0)'	System	28 Sep 2020 16:07:06

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:45', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '803d0d4d-369f-46ee-bb3b-6e7c7ef753f3'	System	28 Sep 2020 16:07:06
User entered 'None (0)'	System	28 Sep 2020 16:07:06

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:48', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '803d0d4d-369f-46ee-bb3b-6e7c7ef753f3'	System	28 Sep 2020 16:07:06
User entered 'None (0)'	System	28 Sep 2020 16:07:06

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

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)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:56', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '803d0d4d-369f-46ee-bb3b-6e7c7ef753f3'	System	28 Sep 2020 16:07:06
User entered 'No (N)'	System	28 Sep 2020 16:07:06

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-28T12:06:59', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '803d0d4d-369f-46ee-bb3b-6e7c7ef753f3'	System	28 Sep 2020 16:07:06
User entered '28 Sep 2020 12:06'	System	28 Sep 2020 16:07:06

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 5'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:36', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fb98a046-252e-4703-a16e-e4be20fef9d6'	System	29 Sep 2020 16:21:57
User entered 'None (0)'	System	29 Sep 2020 16:21:57

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:38', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fb98a046-252e-4703-a16e-e4be20fef9d6'	System	29 Sep 2020 16:21:57
User entered 'None (0)'	System	29 Sep 2020 16:21:57

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:40', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fb98a046-252e-4703-a16e-e4be20fef9d6'	System	29 Sep 2020 16:21:57
User entered 'None (0)'	System	29 Sep 2020 16:21:57

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:42', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fb98a046-252e-4703-a16e-e4be20fef9d6'	System	29 Sep 2020 16:21:57
User entered 'None (0)'	System	29 Sep 2020 16:21:57

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:45', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fb98a046-252e-4703-a16e-e4be20fef9d6'	System	29 Sep 2020 16:21:57
User entered 'None (0)'	System	29 Sep 2020 16:21:57

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:47', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fb98a046-252e-4703-a16e-e4be20fef9d6'	System	29 Sep 2020 16:21:57
User entered 'None (0)'	System	29 Sep 2020 16:21:57

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

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)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:50', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fb98a046-252e-4703-a16e-e4be20fef9d6'	System	29 Sep 2020 16:21:57
User entered 'No (N)'	System	29 Sep 2020 16:21:57

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-29T12:21:52', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fb98a046-252e-4703-a16e-e4be20fef9d6'	System	29 Sep 2020 16:21:57
User entered '29 Sep 2020 12:21'	System	29 Sep 2020 16:21:57

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 6'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:19:57', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '87ff7702-573a-4ef6-8e94-aca4e80482f5'	System	30 Sep 2020 16:20:22
User entered 'None (0)'	System	30 Sep 2020 16:20:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:19:59', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '87ff7702-573a-4ef6-8e94-aca4e80482f5'	System	30 Sep 2020 16:20:22
User entered 'None (0)'	System	30 Sep 2020 16:20:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:20:02', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '87ff7702-573a-4ef6-8e94-aca4e80482f5'	System	30 Sep 2020 16:20:22
User entered 'None (0)'	System	30 Sep 2020 16:20:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:20:05', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '87ff7702-573a-4ef6-8e94-aca4e80482f5'	System	30 Sep 2020 16:20:22
User entered 'None (0)'	System	30 Sep 2020 16:20:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:20:08', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '87ff7702-573a-4ef6-8e94-aca4e80482f5'	System	30 Sep 2020 16:20:22
User entered 'None (0)'	System	30 Sep 2020 16:20:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:20:11', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '87ff7702-573a-4ef6-8e94-aca4e80482f5'	System	30 Sep 2020 16:20:22
User entered 'None (0)'	System	30 Sep 2020 16:20:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

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)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:20:13', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '87ff7702-573a-4ef6-8e94-aca4e80482f5'	System	30 Sep 2020 16:20:22
User entered 'No (N)'	System	30 Sep 2020 16:20:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-09-30T12:20:16', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '87ff7702-573a-4ef6-8e94-aca4e80482f5'	System	30 Sep 2020 16:20:22
User entered '30 Sep 2020 12:20'	System	30 Sep 2020 16:20:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
Data entry locked.	System	25 Sep 2020 14:21:22
User entered 'Day 7'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:22', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fba042b9-e34f-4092-8024-cc742fa7ec31'	System	01 Oct 2020 16:02:48
User entered 'None (0)'	System	01 Oct 2020 16:02:48

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:24', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fba042b9-e34f-4092-8024-cc742fa7ec31'	System	01 Oct 2020 16:02:48
User entered 'None (0)'	System	01 Oct 2020 16:02:48

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:27', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fba042b9-e34f-4092-8024-cc742fa7ec31'	System	01 Oct 2020 16:02:48
User entered 'None (0)'	System	01 Oct 2020 16:02:48

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:29', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fba042b9-e34f-4092-8024-cc742fa7ec31'	System	01 Oct 2020 16:02:48
User entered 'None (0)'	System	01 Oct 2020 16:02:48

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:32', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fba042b9-e34f-4092-8024-cc742fa7ec31'	System	01 Oct 2020 16:02:48
User entered 'None (0)'	System	01 Oct 2020 16:02:48

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:34', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fba042b9-e34f-4092-8024-cc742fa7ec31'	System	01 Oct 2020 16:02:48
User entered 'None (0)'	System	01 Oct 2020 16:02:48

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

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)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:37', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fba042b9-e34f-4092-8024-cc742fa7ec31'	System	01 Oct 2020 16:02:48
User entered 'No (N)'	System	01 Oct 2020 16:02:48

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-10-01T12:02:39', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fba042b9-e34f-4092-8024-cc742fa7ec31'	System	01 Oct 2020 16:02:48
User entered '01 Oct 2020 12:02'	System	01 Oct 2020 16:02:48

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 14:21:22

US3202304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:01:16
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 14:21:22

US3202304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:59:52
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	02 Oct 2020 19:40:53

US3202304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:59:52
User entered '2 Oct 2020'	Lilian Nukuna (b) (4) (b) (4)	02 Oct 2020 19:40:53

US3202304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:59:52
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	02 Oct 2020 19:40:53

US3202304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:59:52
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	02 Oct 2020 19:40:53

US3202304

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:01:04
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	02 Oct 2020 19:40:59

US3202304

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'I'	System	02 Oct 2020 19:40:59

US3202304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:09:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	09 Oct 2020 20:31:28

US3202304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:09:28
User entered '09 Oct 2020'	zackery harmon (b) (4) (b) (4)	09 Oct 2020 20:31:28

US3202304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:09:28
User entered 'Contact Not Made (CONTACT NOT MADE)'	zackery harmon (b) (4) (b) (4)	09 Oct 2020 20:31:28

US3202304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:09:28
User entered 'LVM attempts x3'	zackery harmon (b) (4) (b) (4)	09 Oct 2020 20:31:28

US3202304

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:28:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Lilian Nukuna (b) (4)	16 Oct 2020 14:50:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	09 Oct 2020 20:31:38

US3202304

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '1'	System	16 Oct 2020 14:50:39
User entered empty.	System	09 Oct 2020 20:31:38

US3202304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	21 Feb 2021 17:45:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:36:38
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	16 Oct 2020 14:50:51

US3202304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	21 Feb 2021 17:45:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:36:40
User entered '16 Oct 2020'	Lilian Nukuna (b) (4) (b) (4)	16 Oct 2020 14:50:51

US3202304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:57:20
User closed query 'source contact not made after x1 attempt, please verify and update' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 20:57:18
User signature succeeded.	Mark McKenzie (b) (4)	21 Feb 2021 17:45:20
Query 'source contact not made after x1 attempt, please verify and update' answered with 'done' (Site from CRA).	(b) (4)	
	Teresa Deese (b) (4)	19 Feb 2021 14:42:23
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Teresa Deese (b) (4)	19 Feb 2021 14:42:08
User opened query 'source contact not made after x1 attempt, please verify and update' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 17:29:34
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	16 Oct 2020 14:50:51
	(b) (4)	

US3202304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:57:42
User signature succeeded.	Mark McKenzie (b) (4)	21 Feb 2021 17:45:20
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	(b) (4)	19 Feb 2021 14:42:19
User entered 'X 3 attempts' reason for change: Data Entry Error	Teresa Deese (b) (4)	19 Feb 2021 14:42:19
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	19 Feb 2021 14:42:08
User entered empty.	Lilian Nukuna (b) (4)	16 Oct 2020 14:50:51

US3202304

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:29:41
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	16 Oct 2020 14:50:56

US3202304

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'I'	System	16 Oct 2020 14:50:56

US3202304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:34:55
User entered 'Yes (Y)'	Teresa Deese (b) (4)	23 Oct 2020 19:20:21

US3202304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:34:55
User entered '23 Oct 2020'	Teresa Deese (b) (4)	23 Oct 2020 19:20:21

US3202304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[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 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:34:55
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	23 Oct 2020 19:20:21

US3202304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'VISIT3'	System	23 Oct 2020 19:20:21

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:07
User entered 'Yes (Y)'	Teresa Deese (b) (4)	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:07
User entered '23 Oct 2020'	Teresa Deese (b) (4)	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:07
User entered '09:01'	Teresa Deese (b) (4)	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '23 Oct 2020 09:01'	System	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:07
User entered '36.7' C	Teresa Deese (b) (4)	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:07
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:07
User entered empty.	Teresa Deese (b) (4)	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:07
User entered '84'	Teresa Deese (b) (4)	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'bpm'	System	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:07
User entered '18'	Teresa Deese (b) (4)	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'breaths/min'	System	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:07
User entered '121'	Teresa Deese (b) (4)	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'mmHg'	System	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:07
User entered '82'	Teresa Deese (b) (4)	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'mmHg'	System	23 Oct 2020 19:20:53

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35

US3202304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35

US3202304

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:17
User entered 'No (N)'	Teresa Deese (b) (4)	23 Oct 2020 19:21:01

US3202304

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:17
User entered empty.	Teresa Deese (b) (4)	23 Oct 2020 19:21:01

US3202304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:39
User entered 'Yes (Y)'	Teresa Deese (b) (4)	23 Oct 2020 19:21:59

US3202304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:39
User entered '23 Oct 2020'	Teresa Deese (b) (4)	23 Oct 2020 19:21:59

US3202304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:39
User entered '09:11'	Teresa Deese (b) (4)	23 Oct 2020 19:21:59

US3202304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '23 Oct 2020 09:11'	System	23 Oct 2020 19:21:59

US3202304

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:39:47
User entered 'Yes (Y)'	Teresa Deese (b) (4)	23 Oct 2020 19:22:05

US3202304

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered '1'	System	23 Oct 2020 19:22:05

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 64'	System	28 Aug 2020 18:43:44

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you been exposed to someone with 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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Please 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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Please 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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Please 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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47
Data entry locked.	System	28 Aug 2020 18:43:44
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 18:43:44

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47
Data entry locked.	System	28 Aug 2020 18:43:44
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 71'	System	28 Aug 2020 18:43:44

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you been exposed to someone with 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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Please 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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Please 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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Please 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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47
Data entry locked.	System	28 Aug 2020 18:43:44
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 18:43:44

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47
Data entry locked.	System	28 Aug 2020 18:43:44
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47
Data entry locked.	System	28 Aug 2020 18:43:44
User entered 'Day 78'	System	28 Aug 2020 18:43:44

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you been exposed to someone with 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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Please 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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Please 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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Please 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)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47
Data entry locked.	System	28 Aug 2020 18:43:44
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 18:43:44

US3202304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:50:47
Data entry locked.	System	28 Aug 2020 18:43:44
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 18:43:44

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2020-11-22T10:58:04', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'faa00043-d261-4d04-9967-c71af1e434b5'	System	22 Nov 2020 15:58:19
User entered 'No (N)'	System	22 Nov 2020 15:58:19

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2020-11-22T10:58:08', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'faa00043-d261-4d04-9967-c71af1e434b5'	System	22 Nov 2020 15:58:19
User entered 'No (N)'	System	22 Nov 2020 15:58:19

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-11-22T10:58:15', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'faa00043-d261-4d04-9967-c71af1e434b5'	System	22 Nov 2020 15:58:19
User entered '22 Nov 2020 10:58:15'	System	22 Nov 2020 15:58:19

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2020-11-29T08:46:04', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'cf5313c1-3922-47a7-bf95-a48cddbbaa759'	System	29 Nov 2020 13:46:17
User entered 'No (N)'	System	29 Nov 2020 13:46:17

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2020-11-29T08:46:07', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'cf5313c1-3922-47a7-bf95-a48cddbbaa759'	System	29 Nov 2020 13:46:17
User entered 'No (N)'	System	29 Nov 2020 13:46:17

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-11-29T08:46:12', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'cf5313c1-3922-47a7-bf95-a48cddbbaa759'	System	29 Nov 2020 13:46:17
User entered '29 Nov 2020 08:46:12'	System	29 Nov 2020 13:46:17

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2020-12-06T11:56:12', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '54a2ef22-54a6-41c6-9c9d-70b304d411e9'	System	06 Dec 2020 16:56:24
User entered 'No (N)'	System	06 Dec 2020 16:56:24

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2020-12-06T11:56:16', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '54a2ef22-54a6-41c6-9c9d-70b304d411e9'	System	06 Dec 2020 16:56:24
User entered 'No (N)'	System	06 Dec 2020 16:56:24

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-12-06T11:56:20', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '54a2ef22-54a6-41c6-9c9d-70b304d411e9'	System	06 Dec 2020 16:56:24
User entered '06 Dec 2020 11:56:20'	System	06 Dec 2020 16:56:24

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2020-12-13T08:11:47', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '7019a9ec-61c5-4a1b-acbd-5508f343ecb9'	System	13 Dec 2020 13:12:01
User entered 'No (N)'	System	13 Dec 2020 13:12:01

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2020-12-13T08:11:53', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '7019a9ec-61c5-4a1b-acbd-5508f343ecb9'	System	13 Dec 2020 13:12:01
User entered 'No (N)'	System	13 Dec 2020 13:12:01

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-12-13T08:11:58', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '7019a9ec-61c5-4a1b-acbd-5508f343ecb9'	System	13 Dec 2020 13:12:01
User entered '13 Dec 2020 08:11:58'	System	13 Dec 2020 13:12:01

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2020-12-21T09:07:48', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '03db714b-c8be-48d0-9694-6b90d83af810'	System	21 Dec 2020 14:08:27
User entered 'Yes (Y)'	System	21 Dec 2020 14:08:27

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2020-12-21T09:07:52', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '03db714b-c8be-48d0-9694-6b90d83af810'	System	21 Dec 2020 14:08:27
User entered 'No (N)'	System	21 Dec 2020 14:08:27

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2020-12-21T09:07:56', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '03db714b-c8be-48d0-9694-6b90d83af810'	System	21 Dec 2020 14:08:27
User entered 'No (N)'	System	21 Dec 2020 14:08:27

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2020-12-21T09:08:05', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '03db714b-c8be-48d0-9694-6b90d83af810'	System	21 Dec 2020 14:08:27
User entered 'Yes (Y)'	System	21 Dec 2020 14:08:27

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please 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 (987b5c6c5db1880b)', Time: '2020-12-21T09:08:11', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '03db714b-c8be-48d0-9694-6b90d83af810'	System	21 Dec 2020 14:08:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Dec 2020 14:08:27

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2020-12-21T09:08:15', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '03db714b-c8be-48d0-9694-6b90d83af810'	System	21 Dec 2020 14:08:27
User entered '21 Dec 2020 09:08:15'	System	21 Dec 2020 14:08:27

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-01-04T16:14:13', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f533a2c6-9963-40a7-b75d-cdd2f8a31355'	System	04 Jan 2021 21:14:30
User entered 'No (N)'	System	04 Jan 2021 21:14:30

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-01-04T16:14:18', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f533a2c6-9963-40a7-b75d-cdd2f8a31355'	System	04 Jan 2021 21:14:30
User entered 'No (N)'	System	04 Jan 2021 21:14:30

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-01-04T16:14:23', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f533a2c6-9963-40a7-b75d-cdd2f8a31355'	System	04 Jan 2021 21:14:30
User entered '04 Jan 2021 16:14:23'	System	04 Jan 2021 21:14:30

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-01-11T09:42:09', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '73c79518-d8ba-4007-a87e-7237e1844b95'	System	11 Jan 2021 14:42:19
User entered 'No (N)'	System	11 Jan 2021 14:42:19

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-01-11T09:42:12', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '73c79518-d8ba-4007-a87e-7237e1844b95'	System	11 Jan 2021 14:42:19
User entered 'No (N)'	System	11 Jan 2021 14:42:19

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-01-11T09:42:15', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '73c79518-d8ba-4007-a87e-7237e1844b95'	System	11 Jan 2021 14:42:19
User entered '11 Jan 2021 09:42:15'	System	11 Jan 2021 14:42:19

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-01-17T12:07:47', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fed8422f-f455-4937-aa16-2e27c1d889be'	System	17 Jan 2021 17:07:57
User entered 'No (N)'	System	17 Jan 2021 17:07:57

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-01-17T12:07:51', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fed8422f-f455-4937-aa16-2e27c1d889be'	System	17 Jan 2021 17:07:57
User entered 'No (N)'	System	17 Jan 2021 17:07:57

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-01-17T12:07:54', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fed8422f-f455-4937-aa16-2e27c1d889be' User entered '17 Jan 2021 12:07:54'	System	17 Jan 2021 17:07:57

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-01-31T09:19:35', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fb54aa41-88cf-4062-8b0d-47060462c6ef'	System	31 Jan 2021 14:19:48
User entered 'No (N)'	System	31 Jan 2021 14:19:48

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-01-31T09:19:39', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fb54aa41-88cf-4062-8b0d-47060462c6ef'	System	31 Jan 2021 14:19:48
User entered 'No (N)'	System	31 Jan 2021 14:19:48

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-01-31T09:19:45', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'fb54aa41-88cf-4062-8b0d-47060462c6ef'	System	31 Jan 2021 14:19:48
User entered '31 Jan 2021 09:19:45'	System	31 Jan 2021 14:19:48

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-02-08T07:58:24', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '906e4a4b-6119-4374-9931-41b0e3c0e57f'	System	08 Feb 2021 12:58:33
User entered 'No (N)'	System	08 Feb 2021 12:58:33

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-02-08T07:58:28', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '906e4a4b-6119-4374-9931-41b0e3c0e57f'	System	08 Feb 2021 12:58:33
User entered 'No (N)'	System	08 Feb 2021 12:58:33

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-02-08T07:58:31', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '906e4a4b-6119-4374-9931-41b0e3c0e57f' User entered '08 Feb 2021 07:58:31'	System	08 Feb 2021 12:58:33
	System	08 Feb 2021 12:58:33

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-02-14T09:14:42', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4dfde656-ba15-4476-b69b-1130e3994c86'	System	14 Feb 2021 14:14:50
User entered 'No (N)'	System	14 Feb 2021 14:14:50

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-02-14T09:14:45', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4dfde656-ba15-4476-b69b-1130e3994c86'	System	14 Feb 2021 14:14:50
User entered 'No (N)'	System	14 Feb 2021 14:14:50

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-02-14T09:14:48', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4dfde656-ba15-4476-b69b-1130e3994c86'	System	14 Feb 2021 14:14:50
User entered '14 Feb 2021 09:14:48'	System	14 Feb 2021 14:14:50

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-02-24T09:36:43-05:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4614d085-7d68-4b91-825f-b0e9fefcef5d'	System	24 Feb 2021 14:36:56
User entered 'No (N)'	System	24 Feb 2021 14:36:56

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-02-24T09:36:46-05:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4614d085-7d68-4b91-825f-b0e9fefcef5d'	System	24 Feb 2021 14:36:56
User entered 'No (N)'	System	24 Feb 2021 14:36:56

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-02-24T09:36:50-05:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '4614d085-7d68-4b91-825f-b0e9fefcef5d'	System	24 Feb 2021 14:36:56
User entered '24 Feb 2021 09:36:50'	System	24 Feb 2021 14:36:56

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-03-02T12:45:28-05:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '0f3d8910-0e9d-4135-a391-811891a490b2'	System	02 Mar 2021 17:45:37
User entered 'No (N)'	System	02 Mar 2021 17:45:37

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-03-02T12:45:30-05:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '0f3d8910-0e9d-4135-a391-811891a490b2'	System	02 Mar 2021 17:45:37
User entered 'No (N)'	System	02 Mar 2021 17:45:37

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-03-02T12:45:34-05:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '0f3d8910-0e9d-4135-a391-811891a490b2'	System	02 Mar 2021 17:45:37
User entered '02 Mar 2021 12:45:34'	System	02 Mar 2021 17:45:37

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-03-09T12:01:05-05:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '56593bb3-ecf2-4d0a-bc38-376b3451c391'	System	09 Mar 2021 17:04:32
User entered 'No (N)'	System	09 Mar 2021 17:04:32

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-03-09T12:01:08-05:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '56593bb3-ecf2-4d0a-bc38-376b3451c391'	System	09 Mar 2021 17:04:32
User entered 'No (N)'	System	09 Mar 2021 17:04:32

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-03-09T12:01:11-05:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '56593bb3-ecf2-4d0a-bc38-376b3451c391' User entered '09 Mar 2021 12:01:11'	System	09 Mar 2021 17:04:32

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-03-21T09:10:32-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f2baf887-8389-441b-86e5-eabd4b1e2798'	System	21 Mar 2021 13:10:40
User entered 'No (N)'	System	21 Mar 2021 13:10:40

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-03-21T09:10:35-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f2baf887-8389-441b-86e5-eabd4b1e2798'	System	21 Mar 2021 13:10:40
User entered 'No (N)'	System	21 Mar 2021 13:10:40

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-03-21T09:10:38-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'f2baf887-8389-441b-86e5-eabd4b1e2798'	System	21 Mar 2021 13:10:40
User entered '21 Mar 2021 09:10:38'	System	21 Mar 2021 13:10:40

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-04-07T18:00:24-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6fd564cf-9115-454e-b7c0-23e26d0ce17d'	System	07 Apr 2021 22:03:38
User entered 'Yes (Y)'	System	07 Apr 2021 22:03:38

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-04-07T18:00:28-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6fd564cf-9115-454e-b7c0-23e26d0ce17d'	System	07 Apr 2021 22:03:38
User entered 'No (N)'	System	07 Apr 2021 22:03:38

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-04-07T18:00:31-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6fd564cf-9115-454e-b7c0-23e26d0ce17d'	System	07 Apr 2021 22:03:38
User entered 'No (N)'	System	07 Apr 2021 22:03:38

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-04-07T18:00:39-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6fd564cf-9115-454e-b7c0-23e26d0ce17d'	System	07 Apr 2021 22:03:38
User entered 'Yes (Y)'	System	07 Apr 2021 22:03:38

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Please 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 (987b5c6c5db1880b)', Time: '2021-04-07T18:00:48-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6fd564cf-9115-454e-b7c0-23e26d0ce17d'	System	07 Apr 2021 22:03:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Apr 2021 22:03:38

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-04-07T18:00:53-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6fd564cf-9115-454e-b7c0-23e26d0ce17d'	System	07 Apr 2021 22:03:38
User entered '07 Apr 2021 18:00:53'	System	07 Apr 2021 22:03:38

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-04-13T12:00:30-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9df9ca4e-d11f-47eb-a4bd-30805ad91635'	System	13 Apr 2021 16:02:30
User entered 'No (N)'	System	13 Apr 2021 16:02:30

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-04-13T12:00:33-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9df9ca4e-d11f-47eb-a4bd-30805ad91635'	System	13 Apr 2021 16:02:30
User entered 'No (N)'	System	13 Apr 2021 16:02:30

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-04-13T12:00:36-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '9df9ca4e-d11f-47eb-a4bd-30805ad91635'	System	13 Apr 2021 16:02:30
User entered '13 Apr 2021 12:00:36'	System	13 Apr 2021 16:02:30

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-04-28T09:17:18-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6a4eef01-4c62-4965-9ea3-1d13f2a5b13c'	System	29 Apr 2021 00:26:10
User entered 'No (N)'	System	29 Apr 2021 00:26:10

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-04-28T09:17:21-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6a4eef01-4c62-4965-9ea3-1d13f2a5b13c'	System	29 Apr 2021 00:26:10
User entered 'No (N)'	System	29 Apr 2021 00:26:10

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-04-28T09:17:24-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '6a4eef01-4c62-4965-9ea3-1d13f2a5b13c'	System	29 Apr 2021 00:26:10
User entered '28 Apr 2021 09:17:24'	System	29 Apr 2021 00:26:10

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[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 (987b5c6c5db1880b)', Time: '2021-05-02T09:37:23-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '120094ea-943c-41bd-88a2-00f9f5f78e10'	System	02 May 2021 13:37:35
User entered 'No (N)'	System	02 May 2021 13:37:35

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Have you been exposed to someone with 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 (987b5c6c5db1880b)', Time: '2021-05-02T09:37:27-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '120094ea-943c-41bd-88a2-00f9f5f78e10'	System	02 May 2021 13:37:35
User entered 'No (N)'	System	02 May 2021 13:37:35

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-05-02T09:37:31-04:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: '120094ea-943c-41bd-88a2-00f9f5f78e10'	System	02 May 2021 13:37:35
User entered '02 May 2021 09:37:31'	System	02 May 2021 13:37:35

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 01:50:47

US3202304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:50:47
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 01:50:47

US3202304

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:45:32

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)	30 Apr 2021 12:16:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-03-02T12:45:42-05:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a5bb513c-ddcb-40c2-82cc-542aca36ddaa'	System	02 Mar 2021 17:45:50
User entered 'No (N)'	System	02 Mar 2021 17:45:50

US3202304

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:45:32

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987b5c6c5db1880b)', Time: '2021-03-02T12:45:49-05:00', User OID: 'PatientReportedOutcome (US3202304)', ODM File OID: 'a5bb513c-ddcb-40c2-82cc-542aca36ddaa'	System	02 Mar 2021 17:45:50
User entered '02 Mar 2021 12:45:49'	System	02 Mar 2021 17:45:50

US3202304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:12:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 19:34:32

US3202304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:12:08
User entered '20 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 19:34:32

US3202304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:12:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Nov 2020 19:34:32

US3202304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:12:08
User entered 'LEFT MESSAGE FOR DAY 85 PHONE CALL	(b) (4), (b) (6)	20 Nov 2020 19:54:34
Sub called back later on 20 nov 2020' reason for change: Data Entry Error		
User entered 'LEFT MESSAGE FOR DAY 85 PHONE CALL'	(b) (4), (b) (6)	20 Nov 2020 19:34:32

US3202304

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:12:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 19:34:38

US3202304

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:38:35
User entered 'I'	System	20 Nov 2020 19:34:38

US3202304

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:47:12
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Mar 2021 21:04:50

US3202304

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:47:12
User entered '22 Dec 2020'	Erica Osmundsen (b) (4)	09 Mar 2021 21:04:50

US3202304

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:47:12
User entered 'Contact Made (CONTACT MADE)'	Erica Osmundsen (b) (4)	09 Mar 2021 21:04:50

US3202304

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:47:12
User entered empty.	Erica Osmundsen (b) (4)	09 Mar 2021 21:04:50

US3202304

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:47:22
User closed query 'source = contact made on 22Dec20, please verify and update' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 15:47:20
Query 'source = contact made on 22Dec20, please verify and update' answered with 'updated' (Site from CRA).	Erica Osmundsen (b) (4)	09 Mar 2021 21:04:58
User opened query 'source = contact made on 22Dec20, please verify and update' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 20:59:43
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:26:26

US3202304

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User entered 'I'	System	25 Jan 2021 21:26:26

US3202304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:15
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:26:39

US3202304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:15
User entered '25 Jan 2021'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:26:39

US3202304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:15
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:26:39

US3202304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:15
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:26:39

US3202304

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:21
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:26:45

US3202304

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User entered 'I'	System	25 Jan 2021 21:26:45

US3202304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:20:19
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Mar 2021 21:06:02

US3202304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:20:19
User entered '23 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Mar 2021 21:06:37
User entered '22 Feb 2021'	Erica Osmundsen (b) (4)	09 Mar 2021 21:06:02

US3202304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:20:19
User entered 'Contact Made (CONTACT MADE)'	Erica Osmundsen (b) (4)	09 Mar 2021 21:06:02

US3202304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:20:19
User entered 'completed with OL-DOSE 2' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Mar 2021 21:06:50
User entered empty.	Erica Osmundsen (b) (4)	09 Mar 2021 21:06:02

US3202304

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:20:24
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Mar 2021 21:06:55

US3202304

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:29
User entered 'I'	System	09 Mar 2021 21:06:55

US3202304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered 'Yes (Y)'	Teresa Deese (b) (4)	25 Mar 2021 16:27:47

US3202304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered '25 Mar 2021'	(b) (4) Teresa Deese (b) (4)	25 Mar 2021 16:27:47

US3202304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

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 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	25 Mar 2021 16:27:47

US3202304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
User entered 'VISIT4'	System	25 Mar 2021 16:27:47

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
User entered empty.	System	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered empty.	(b) (4)	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
User entered empty.	System	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
User entered empty.	System	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered empty.	(b) (4)	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
User entered empty.	System	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
User entered empty.	System	01 Apr 2021 00:41:57

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48

US3202304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48

US3202304

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered 'No (N)'	(b) (4)	
	Teresa Deese (b) (4)	25 Mar 2021 16:27:37

US3202304

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	25 Mar 2021 16:27:37

US3202304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
User closed query 'Per GCL LAB Recon: Immunogenicity: GCL has an 25MAR2021 sample Barcode# 1F652865169 labelled as OL-D57. If Visit 4 DAY 209 and OL-D57 was performed on the same day then, Per CCG, OL-phase sample is collected but Immunogenicity form is updated under both the visit as yes. Please confirm if the Visit 4Day209 and OL-D57 are overlapping visit then update the Immunogenicity data under OL-D57 visit or else confirm the correct visit label if the visits are not overlapping. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 11:47:24
Query 'Per GCL LAB Recon: Immunogenicity: GCL has an 25MAR2021 sample Barcode# 1F652865169 labelled as OL-D57. If Visit 4 DAY 209 and OL-D57 was performed on the same day then, Per CCG, OL-phase sample is collected but Immunogenicity form is updated under both the visit as yes. Please confirm if the Visit 4Day209 and OL-D57 are overlapping visit then update the Immunogenicity data under OL-D57 visit or else confirm the correct visit label if the visits are not overlapping. Thank you.' answered with 'UPDATED OL-D57 IN EDC AS VISITS WERE OVERLAPPING ON THIS DATE' (Site from DM).	Erica Osmundsen (b) (4)	16 Apr 2021 13:20:26
User opened query 'Per GCL LAB Recon: Immunogenicity: GCL has an 25MAR2021 sample Barcode# 1F652865169 labelled as OL-D57. If Visit 4 DAY 209 and OL-D57 was performed on the same day then, Per CCG, OL-phase sample is collected but Immunogenicity form is updated under both the visit as yes. Please confirm if the Visit 4Day209 and OL-D57 are overlapping visit then update the Immunogenicity data under OL-D57 visit or else confirm the correct visit label if the visits are not overlapping. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:01:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34

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EAB) (1725)

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US3202304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Teresa Deese (b) (4)	25 Mar 2021 16:27:24

US3202304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered '25 Mar 2021'	(b) (4)	
	Teresa Deese (b) (4)	25 Mar 2021 16:27:24

US3202304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered '11:55'	(b) (4)	
	Teresa Deese (b) (4)	25 Mar 2021 16:27:24

US3202304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
User entered '25 Mar 2021 11:55'	System	25 Mar 2021 16:27:24

US3202304

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered 'Yes (Y)'	Teresa Deese (b) (4)	25 Mar 2021 16:27:29

US3202304

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:50:48
User entered 'I'	System	25 Mar 2021 16:27:29

US3202304

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

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:01:26
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 18:15:38

US3202304

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

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:01:26
User entered '26 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 18:15:38

US3202304

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

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[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 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:01:26
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	26 Jan 2021 18:15:38

US3202304

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

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 18:15:38

US3202304

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:32

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:01:37
User entered '26 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 18:15:57

US3202304

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:32

[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 19:02:10
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:12:25
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:01:32
User entered '0'	(b) (4) Teresa Deese (b) (4)	22 Apr 2021 17:24:55
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:25:24

US3202304

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:32

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:01:37
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 18:15:57

US3202304

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:32

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:12:25
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 18:54:57
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:01:32
Query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'done' (Site from DM).	(b) (4)	
	Teresa Deese (b) (4)	22 Apr 2021 17:25:14
User entered 'Amendment 6 or later (Amendment 6 or later)'	Teresa Deese (b) (4)	22 Apr 2021 17:24:55
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 09:00:10
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:25:24

US3202304

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:32

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:01:37
User entered '26 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 18:15:57

US3202304

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:32

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:01:37
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	26 Jan 2021 18:15:57

US3202304

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:32

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:01:37
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	26 Jan 2021 18:15:57

US3202304

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:32

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:01:37
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	26 Jan 2021 18:15:57

US3202304

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:32

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:01:37
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 18:15:57

US3202304

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:32

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered '1'	System	26 Jan 2021 18:15:57

US3202304

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:32

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'I'	System	26 Jan 2021 18:15:57

US3202304

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered empty.	System	26 Jan 2021 18:17:19
DataPoint set to visible.	System	26 Jan 2021 18:15:57

US3202304

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered empty.	System	26 Jan 2021 18:17:19
DataPoint set to visible.	System	26 Jan 2021 18:15:57

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '26 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '09:36'	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered '26 Jan 2021 09:36'	System	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '37' C	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '68'	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'bpm'	System	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '14'	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'breaths/min'	System	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '138'	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'mmHg'	System	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '82'	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'mmHg'	System	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 18:17:19

US3202304

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered empty.	System	26 Jan 2021 18:17:19
DataPoint set to visible.	System	26 Jan 2021 18:15:57

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '26 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '10:26'	Teresa Deese (b) (4)	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered '26 Jan 2021 10:26'	System	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '36.9' C	Teresa Deese (b) (4)	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '76'	Teresa Deese (b) (4)	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'bpm'	System	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '16'	Teresa Deese (b) (4)	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'breaths/min'	System	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '148'	Teresa Deese (b) (4)	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'mmHg'	System	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:02:19
User entered '85'	Teresa Deese (b) (4)	26 Jan 2021 18:19:01

US3202304

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'mmHg'	System	26 Jan 2021 18:19:01

US3202304

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:23
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 18:19:07

US3202304

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:23
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 18:19:07

US3202304

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

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:37
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 18:19:24

US3202304

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

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:37
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 18:19:24

US3202304

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

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:37
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 18:19:24

US3202304

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

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'mRNA-1273'	System	26 Jan 2021 18:19:24
DataPoint set to visible.	System	26 Jan 2021 18:15:57

US3202304

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

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:37
User entered '26 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 18:19:24

US3202304

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

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:37
User entered '09:51'	Teresa Deese (b) (4)	26 Jan 2021 18:19:24

US3202304

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

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered '26 Jan 2021 09:51'	System	26 Jan 2021 18:19:24

US3202304

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

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:37
User entered 'Left Arm (LEFT ARM)'	Teresa Deese (b) (4)	26 Jan 2021 18:19:24

US3202304

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

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:08:37
User entered 'ONCE'	System	26 Jan 2021 18:19:24

US3202304

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

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'INTRAMUSCULAR'	System	26 Jan 2021 18:19:24

US3202304

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:43
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 18:19:37

US3202304

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:43
User entered '26 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 18:19:37

US3202304

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:43
User entered '09:49'	Teresa Deese (b) (4)	26 Jan 2021 18:19:37

US3202304

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered '26 Jan 2021 09:49'	System	26 Jan 2021 18:19:37

US3202304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:45:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:48
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 18:19:47

US3202304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:45:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:48
User entered '26 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 18:19:47

US3202304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:45:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:48
User entered '09:47'	Teresa Deese (b) (4)	26 Jan 2021 18:19:47

US3202304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:45:32

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered '26 Jan 2021 09:47'	System	26 Jan 2021 18:19:47

US3202304

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

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:08:54
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 18:19:52

US3202304

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

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:10
User entered 'I'	System	26 Jan 2021 18:19:52

US3202304

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:58
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	08 Feb 2021 21:04:51

US3202304

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:58
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User closed query 'please file source as not present in the chart' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 15:47:39
Query 'please file source as not present in the chart' answered with 'done' (Site from CRA).	zackery harmon (b) (4)	10 Mar 2021 15:06:45
User opened query 'please file source as not present in the chart' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:13:40
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 08:49:26
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'schedule conflict between site & subject' (Site from System).	Teresa Deese (b) (4)	19 Feb 2021 14:43:19
Amendment Manager: User opened query 'OL Safety System Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Feb 2021 01:23:55
User entered '8 Feb 2021'	Lilian Nukuna (b) (4)	08 Feb 2021 21:04:51

US3202304

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:58
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	08 Feb 2021 21:04:51

US3202304

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:58
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered empty.	Lilian Nukuna (b) (4)	08 Feb 2021 21:04:51

US3202304

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:37:02
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	08 Feb 2021 21:04:57

US3202304

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'I'	System	08 Feb 2021 21:04:57

US3202304

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered '1'	System	08 Feb 2021 21:04:57
DataPoint set to visible.	System	08 Feb 2021 21:04:57

US3202304

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:06:01

US3202304

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:38
User entered '23 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:06:01

US3202304

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[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 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:38
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Feb 2021 20:06:01

US3202304

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'OLD29'	System	24 Feb 2021 20:06:01

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '23 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '10:05'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered '23 Feb 2021 10:05'	System	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '37.1' C	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '81'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'bpm'	System	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '16'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'breaths/min'	System	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '119'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'mmHg'	System	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '78'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'mmHg'	System	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '23 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '11:03'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered '23 Feb 2021 11:03'	System	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '36.7' C	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '54'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'bpm'	System	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '17'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'breaths/min'	System	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '134'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'mmHg'	System	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:17:57
User entered '81'	(b) (4), (b) (6)	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'mmHg'	System	24 Feb 2021 20:11:08

US3202304

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:18:40
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 20:11:30

US3202304

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:18:40
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:11:30

US3202304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:18:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:12:01

US3202304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:18:53
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:12:01

US3202304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:18:53
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:12:01

US3202304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'mRNA-1273'	System	24 Feb 2021 20:12:01
DataPoint set to visible.	System	08 Feb 2021 21:04:57

US3202304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:18:53
User entered '23 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:12:01

US3202304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:18:53
User entered '10:28'	(b) (4), (b) (6)	24 Feb 2021 20:12:01

US3202304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered '23 Feb 2021 10:28'	System	24 Feb 2021 20:12:01

US3202304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:18:53
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	24 Feb 2021 20:12:01

US3202304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:18:53
User entered 'ONCE'	System	24 Feb 2021 20:12:01

US3202304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:32

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 20:12:01

US3202304

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:18:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:12:06

US3202304

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'I'	System	24 Feb 2021 20:12:06

US3202304

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Mar 2021 21:07:27

US3202304

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered '2 Mar 2021'	Erica Osmundsen (b) (4)	09 Mar 2021 21:07:27

US3202304

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Erica Osmundsen (b) (4)	09 Mar 2021 21:07:27

US3202304

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered empty.	Erica Osmundsen (b) (4)	09 Mar 2021 21:07:27

US3202304

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:35
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Mar 2021 21:07:31

US3202304

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:52
User entered 'I'	System	09 Mar 2021 21:07:31

US3202304

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:08
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:19:33

US3202304

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:08
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered '25 Mar 2021'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:19:33

US3202304

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:08
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered 'Clinic (Clinic)'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:19:33

US3202304

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
User entered 'OLD57'	System	16 Apr 2021 13:19:33

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:50
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:50
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:50
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
User entered empty.	System	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:50
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:50
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:50
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:50
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
User entered empty.	System	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:50
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
User entered empty.	System	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:50
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
User entered empty.	System	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:50
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
User entered empty.	System	16 Apr 2021 13:19:49

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32

US3202304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32

US3202304

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:56
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:19:52

US3202304

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:56
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	16 Apr 2021 13:19:52

US3202304

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:51:03
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:20:03

US3202304

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:51:03
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered '25 Mar 2021'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:20:03

US3202304

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:51:03
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:43:15
User entered '11:55' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:20:17
User entered '11:05'	Erica Osmundsen (b) (4)	16 Apr 2021 13:20:03

US3202304

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:32
User entered '25 Mar 2021 11:55'	System	16 Apr 2021 13:20:17
User entered '25 Mar 2021 11:05'	System	16 Apr 2021 13:20:03

US3202304

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:45:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:29
User closed query 'Per CDM RQ: Per query response "did you check AEs & con proc?", however if the data is updated please provide location of update such as the form/log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:46:21
Query 'Per CDM RQ: Per query response "did you check AEs & con proc?", however if the data is updated please provide location of update such as the form/log line number. Thank you.' answered with 'check the AEs & con proc dates' (Site from DM).	Teresa Deese (b) (4)	06 Apr 2021 13:28:14
User opened query 'Per CDM RQ: Per query response "did you check AEs & con proc?", however if the data is updated please provide location of update such as the form/log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 10:39:09
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 117, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 10:39:09
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 117, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'did you check AEs & con proc?' (Site from DM).	Teresa Deese (b) (4)	30 Mar 2021 15:57:37

US3202304

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:45:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 117, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 13:35:01
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:14:46
User closed query 'Source note indicates fall due to syncope and subsequent medication change. Please confirm whether or not event meets MAAE criteria for AE capture. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:46:48
Query 'Source note indicates fall due to syncope and subsequent medication change. Please confirm whether or not event meets MAAE criteria for AE capture. ' answered with 'done' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:56:08
User opened query 'Source note indicates fall due to syncope and subsequent medication change. Please confirm whether or not event meets MAAE criteria for AE capture. ' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:25:48
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:18:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	22 Dec 2020 21:37:39
User entered 'No (N)'	Tiffany Jewell (b) (4)	31 Aug 2020 13:00:29

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:14:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:02
User entered	System	23 Dec 2020 14:28:13
'USA-US128-2020-mRNA-1273-P301000015'		
User entered 'New'	(b) (4), (b) (6)	23 Dec 2020 14:28:13

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Dec 2020 16:06:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Dec 2020 16:06:49
Data point term sent to Coder	System	22 Dec 2020 21:48:21
User entered 'WORSENING OF ENLARGED PROSTATE (BENIGN PROSTATIC HYPERPLASIA)'	Erica Osmundsen (b) (4) (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'No (N)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'No (N)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 19:34:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 18:15:35
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '01 Dec 2020'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'No (N)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 17:32:06
User closed query 'AE source log = 18Dec20, please verify' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:32:05
Query 'AE source log = 18Dec20, please verify' answered with 'updated per source' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:56:22
User entered '18 Dec 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Feb 2021 14:43:02
User opened query 'AE source log = 18Dec20, please verify' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 18:14:56
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:39
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:28
User closed query 'Per DM CLR: Please review the End date of this AE as it was noted that a procedure of Prostatectomy was performed on 17Dec2020. Please reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 22:12:50
Query 'Per DM CLR: Please review the End date of this AE as it was noted that a procedure of Prostatectomy was performed on 17Dec2020. Please reconcile and update accordingly. Otherwise, clarify.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	26 Jan 2021 16:10:57
User entered '17 Dec 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Jan 2021 16:10:51
User opened query 'Per DM CLR: Please review the End date of this AE as it was noted that a procedure of Prostatectomy was performed on 17Dec2020. Please reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 19:08:49
User entered '18 Dec 2020'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

Severity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
User closed query 'PV Query: Since the subject was hospitalized for the event of worsening of enlarged prostate (BPH), appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:33:40
Query 'PV Query: Since the subject was hospitalized for the event of worsening of enlarged prostate (BPH), appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:09:34
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Teresa Deese (b) (4)	11 Feb 2021 21:58:00
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:36
User opened query 'PV Query: Since the subject was hospitalized for the event of worsening of enlarged prostate (BPH), appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 16:50:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	28 Jan 2021 18:14:28
	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:42
	(b) (4), (b) (6)	
User closed query 'please confirm documented in source. ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:38:40
Query 'please confirm documented in source. ' answered with 'clarified' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:43:46
	(b) (4), (b) (6)	
User opened query 'please confirm documented in source. ' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 18:17:42
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 18:17:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:28
	(b) (4), (b) (6)	
User entered 'I'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '17 Dec 2020'	Erica Osmundsen (b) (4) 	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '18 Dec 2020'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'No (N)'	Erica Osmundsen (b) (4) 	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Erica Osmundsen (b) (4) 	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4) 	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4) 	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding medication that match this AE during this time frame. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 22:13:24
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding medication that match this AE during this time frame. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	26 Jan 2021 16:08:38
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding medication that match this AE during this time frame. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 19:08:34
User entered 'I'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'I'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[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 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
User closed query 'PV Query: Since the subject was hospitalized for the event of worsening of enlarged prostate (BPH), appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:48:19
Query 'PV Query: Since the subject was hospitalized for the event of worsening of enlarged prostate (BPH), appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	19 Feb 2021 14:44:06
User opened query 'PV Query: Since the subject was hospitalized for the event of worsening of enlarged prostate (BPH), appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 13:47:30
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) (6)	09 Feb 2021 13:05:20
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 08/FEB/2021' (Site from Safety).	Erica Osmundsen (b) (4)	08 Feb 2021 15:23:02
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)	03 Feb 2021 15:40:59
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 17:33:45
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)	27 Jan 2021 17:33:42
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'none' (Site from Safety).	Teresa Deese (b) (4)	26 Jan 2021 16:10:33
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 'none noted in records' (Site from Safety).	Teresa Deese (b) (4)	26 Jan 2021 16:10:24
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 15:17:44
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)	29 Dec 2020 15:16:50
User entered 'SUBJECT REPORTED HAVING PROSTATECTOMY DUE TO WORSENING OF THIS CONDITION. WAS KEPT IN HOSPITAL OVERNIGHT'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Dec 2020 21:48:19

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:10:09
User closed query 'Please confirm what symptoms subject had and should an illness visit have been done?' ' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 14:10:07
Query 'Please confirm what symptoms subject had and should an illness visit have been done?' ' answered with 'sore throat <48 hrs' (Site from CRA).	Teresa Deese (b) (4)	11 Feb 2021 21:58:20
User opened query 'Please confirm what symptoms subject had and should an illness visit have been done?' ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:51:40
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:50:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:28
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pharyngitis streptococcal, LLT: Streptococcal pharyngitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 16:13:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 16:13:51
Data point term sent to Coder	System	26 Jan 2021 16:12:51
User entered 'strep throat'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '28 Dec 2020'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User entered empty.	System	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:39:13
User closed query 'treatment con med end date = 06Jan2021 but AE source documentation end date= 30Dec2020, please verify and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:39:11
Query 'treatment con med end date = 06Jan2021 but AE source documentation end date= 30Dec2020, please verify and reconcile. ' answered with 'updated end date per treatment duration, subject's symptoms improved before the course of antibiotics was finished' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:42:15
User opened query 'treatment con med end date = 06Jan2021 but AE source documentation end date= 30Dec2020, please verify and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:16:50
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 19:15:57
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '6 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User entered empty.	System	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'None (NONE)'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'I'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[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 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User entered '0'	System	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06
User entered 'I'	System	26 Jan 2021 16:12:13

US3202304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:06

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:10:24
User closed query 'AE source log term = lacerations only, please reconcile' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 14:10:21
Query 'AE source log term = lacerations only, please reconcile' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	11 Feb 2021 21:58:56
User opened query 'AE source log term = lacerations only, please reconcile' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:39:56
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:39:30
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Laceration of hand - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 18:34:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 18:34:51
Data point term sent to Coder	System	26 Jan 2021 16:13:52
User entered 'lacerations to both hands'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '14 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User entered empty.	System	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:10:31
User closed query 'source = 14Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 14:10:29
Query 'source = 14Jan2021, please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	11 Feb 2021 21:59:24
User entered '14 Jan 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	11 Feb 2021 21:59:18
User opened query 'source = 14Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:42:02
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:40:25
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '26 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:10:37
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:40:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User entered empty.	System	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:10:36
User closed query 'AE source log = grade 3/Severe, please verify' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 14:10:33
Query 'AE source log = grade 3/Severe, please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	11 Feb 2021 21:59:27
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Teresa Deese (b) (4)	11 Feb 2021 21:59:18
User opened query 'AE source log = grade 3/Severe, please verify' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:41:30
User closed query 'two AE source logs are present; one with mild and other with severe intensity. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:41:30
Query 'two AE source logs are present; one with mild and other with severe intensity. Please reconcile.' answered with 'deleted duplicate entry with mild severity from source' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:38:52
User opened query 'two AE source logs are present; one with mild and other with severe intensity. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:37:02
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 19:35:54
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'None (NONE)'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:09
DataPoint Un-verified.	Erica Osmundsen (b) (4)	08 Feb 2021 14:39:03
User entered '1' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Feb 2021 14:39:03
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:42:21
User closed query 'please verify as there is no treatment procedure documented' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:42:15
Query 'please verify as there is no treatment procedure documented' answered with 'entry error--cephalexin started so concomitant medication was intended selection' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:39:28
User entered '0' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Feb 2021 14:39:03
User opened query 'please verify as there is no treatment procedure documented' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:18:34
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered '1'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[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 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:14:28
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User entered '0'	System	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07
User entered '1'	System	26 Jan 2021 16:13:40

US3202304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:07

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope hypotensive - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 19:21:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 19:21:00
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 14:10:55
User closed query 'AE source log does not match, please confirm reconciled.' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 14:10:53
Query 'AE source log does not match, please confirm reconciled.' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	11 Feb 2021 22:00:00
User opened query 'AE source log does not match, please confirm reconciled.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:43:29
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:43:23
Data point term sent to Coder	System	08 Feb 2021 14:38:00
User entered 'SYNCOPE (hypotensive episode)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:43:25
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:43:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:43:39
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:43:40
User entered '14 Jan 2021'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:43:43
User entered empty.	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User entered empty.	System	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:43:45
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:43:47
User entered '14 Jan 2021'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:43:50
User entered empty.	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User entered empty.	System	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:43:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:43:53
User entered 'No (N)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:43:56
User entered '0'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:35
User entered '0'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:37
User entered '0'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:39
User entered empty.	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:43
User entered empty.	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:45
User entered empty.	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:47
User entered empty.	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:49
User entered '0'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:52
User entered '0'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:53
User entered '0'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:56
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:58
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:45:01
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:45:05
User entered 'l'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:45:07
User entered '0'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:45:10
User entered '0'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:45:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[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 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:45:16
User entered empty.	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:45:18
User entered 'action taken was to d/c losartan'	Erica Osmundsen (b) (4)	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User entered '0'	System	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12
User entered 'I'	System	08 Feb 2021 14:37:39

US3202304

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:44:12

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 19:14:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 19:14:57
Data point term sent to Coder	System	14 Apr 2021 19:14:06
User entered 'RIGHT KNEE PAIN'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered 'No (N)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered 'No (N)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered '01 Apr 2021'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered 'No (N)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered '0'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered '0'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered '0'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered '0'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered '0'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered '0'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

None

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered '0'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered 'I'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered '0'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:25:50
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Apr 2021 19:13:25

US3202304

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 19:13:25

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
Query 'Line 9 appears to be a duplication of line 5, please verify and update' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:17:03
User opened query 'Line 9 appears to be a duplication of line 5, please verify and update' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:31:39
User closed query 'source also = Aspirin 81 mg daily as a prior medication, please verify' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:22:51
User closed query 'Please document source for end dates of d/c con meds that are noted to end 20Dec2020. Also, hospital records indicate subject was also taking Losartan and Melatonin which are not in con meds. Please provide source for start date of Losartan' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:22:49
Query 'source also = Aspirin 81 mg daily as a prior medication, please verify' answered with 'patient denied taking this because of his GERD--mentioned once in medical record--likely error in record' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 15:00:36
Query 'Please document source for end dates of d/c con meds that are noted to end 20Dec2020. Also, hospital records indicate subject was also taking Losartan and Melatonin which are not in con meds. Please provide source for start date of Losartan' answered with 'done' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:56:32
User opened query 'source also = Aspirin 81 mg daily as a prior medication, please verify' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:30:11
User opened query 'Please document source for end dates of d/c con meds that are noted to end 20Dec2020. Also, hospital records indicate subject was also taking Losartan and Melatonin which are not in con meds. Please provide source for start date of Losartan' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:15:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:11:45
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:42:37

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:46:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:46:51
Data point term sent to Coder	System	31 Aug 2020 12:45:14
User entered 'Citalopram'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:49:52
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Depression'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered '40'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 12:09:54
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	28 Sep 2020 14:49:52
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 07:21:25
User entered 'UN Jan 2019'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Tiffany Jewell (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 12:44:34

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:15:41
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:47:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:47:45
Data point term sent to Coder	System	31 Aug 2020 12:46:16
User entered 'Tamsulosin'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:15:42
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:15:44
User entered 'Enlarged Prostate'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:23:15
User closed query 'Per CDM: Please verify the dose per administration (.8) is not acceptable. Please review and update (e.g. 0.8)appropriately.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 09:09:17
Query 'Per CDM: Please verify the dose per administration (.8) is not acceptable. Please review and update (e.g. 0.8)appropriately.' answered with 'done' (Site from DM).	Erica Osmundsen (b) (4)	08 Feb 2021 14:45:28
User entered '0.8' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Feb 2021 14:45:24
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 16:50:14
User opened query 'Per CDM: Please verify the dose per administration (.8) is not acceptable. Please review and update (e.g. 0.8)appropriately.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:09:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:15:46
User entered '.8'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:15:47
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:15:50
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:15:52
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:15:54
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:15:56
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:15:57
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:15:59
User entered 'UN UNK 2004'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:01
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:50:45
DataPoint Un-verified.	Lilian Nukuna (b) (4)	25 Jan 2021 21:27:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Lilian Nukuna (b) (4)	25 Jan 2021 21:27:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:02
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:23:34
User closed query 'source = 17Dec2020, Please verify' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:23:30
Query 'source = 17Dec2020, Please verify' answered with 'corrected' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:47:52
User entered '17 Dec 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Feb 2021 14:47:45
User opened query 'source = 17Dec2020, Please verify' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 16:50:39
DataPoint Un-verified.	Lilian Nukuna (b) (4)	25 Jan 2021 21:27:55
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4) Lilian Nukuna (b) (4)	25 Jan 2021 21:27:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:04
User entered empty.	Tiffany Jewell (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:07
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User entered '1'	System	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User entered '1'	System	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:27
User entered '804 (804)'	System	31 Aug 2020 12:46:10

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL, PRODUCTSYNONYM: CIALIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:47:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:47:46
Data point term sent to Coder	System	31 Aug 2020 12:47:17
User entered 'Cialis'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Erectile Dysfunction'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered '5'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:11:58
User closed query 'source = daily please verify' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:11:55
Query 'source = daily please verify' answered with 'updated' (Site from CRA).	zackery harmon (b) (4) (b) (4)	02 Dec 2020 22:25:15
User entered 'once daily (QD)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	02 Dec 2020 22:25:10
User opened query 'source = daily please verify' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:17:37
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:17:13
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'as needed (PRN)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'I'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Tiffany Jewell (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Dec 2020 22:25:10
User entered empty.	System	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Dec 2020 22:25:10
User entered empty.	System	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Dec 2020 22:25:10
User entered empty.	System	31 Aug 2020 12:47:06

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:49:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:49:05
Data point term sent to Coder	System	04 Mar 2021 16:30:06
Coding entries removed.	Teresa Deese (b) (4)	04 Mar 2021 16:29:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:14
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 15:44:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 15:44:34
Data point term sent to Coder	System	31 Aug 2020 12:49:19
User entered 'Testosterone Pellets'	Tiffany Jewell (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:51:08
User closed query 'please verify' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:12:36
Query 'please verify' answered with 'verified' (Site from CRA).	zackery harmon (b) (4) (b) (4)	02 Dec 2020 22:28:55
User opened query 'please verify' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:18:26
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:18:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Hypogonadism'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:39:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User closed query 'source = 200 mg per 3 months, please verify' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 15:46:22
Query 'source = 200 mg per 3 months, please verify' answered with 'this is a compounded Rx' (Site from CRA).	Teresa Deese (b) (4)	12 Mar 2021 21:06:17
User opened query 'source = 200 mg per 3 months, please verify' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:24:33
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 10:11:17
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	04 Mar 2021 16:29:28
DataPoint Un-verified.	Teresa Deese (b) (4)	04 Mar 2021 16:29:20
User entered '10' reason for change: Data Entry Error	Teresa Deese (b) (4)	04 Mar 2021 16:29:20
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 05:17:55
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:00
User closed query 'please confirm dose is documented in source' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:23:54
Query 'please confirm dose is documented in source' answered with 'done' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:51:25
User opened query 'please confirm dose is documented in source' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 16:51:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of pouch count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 20:10:04
Query 'Per DM CLR: Please provide the actual dose for this medication instead of pouch count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	26 Jan 2021 15:53:36
User entered '200' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Jan 2021 15:53:30
User closed query 'source = 1 pouch please verify' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:12:18
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of pouch count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:21:31
Query 'source = 1 pouch please verify' answered with 'verified' (Site from CRA).	zackery harmon (b) (4)	02 Dec 2020 22:29:01
User entered '1' reason for change: Data Entry Error	zackery harmon (b) (4)	02 Dec 2020 22:25:39
User opened query 'source = 1 pouch please verify' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:20:51
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:19:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:14
User closed query 'Per CDM: As per CCG Page no: 36, Please Kindly review and update text field accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:07:52
Query 'Per CDM: As per CCG Page no: 36, Please Kindly review and update text field accordingly. Thank you.' answered with 'Updated' (Site from DM).	Tiffany Jewell (b) (4)	28 Sep 2020 14:50:43
User entered 'UNK' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	28 Sep 2020 14:50:37

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: As per CCG Page no: 36, Please Kindly review and update text field accordingly. Thank you.' (Site from DM). User entered 'Unknown'	(b) (4), (b) (6) (b) (4)	04 Sep 2020 16:16:14
	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:39:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Un-verified.	(b) (4) Teresa Deese (b) (4)	04 Mar 2021 16:29:20
User entered 'Other (OTHER)' reason for change: Data Entry Error	Teresa Deese (b) (4)	04 Mar 2021 16:29:20
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:05
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	26 Jan 2021 15:54:18
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	26 Jan 2021 15:53:30
DataPoint Un-verified.	Teresa Deese (b) (4)	26 Jan 2021 15:53:30
User entered 'mg (mg)' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Jan 2021 15:53:30
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:12:31
User closed query 'source = 1 pouch please verify' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:12:22
Query 'source = 1 pouch please verify' answered with 'verified' (Site from CRA).	zackery harmon (b) (4)	02 Dec 2020 22:29:06
User opened query 'source = 1 pouch please verify' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:21:29
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:19:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Other (OTHER)'	Tiffany Jewell (b) (4)	31 Aug 2020 12:48:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:39:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 21:24:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:50
DataPoint Un-verified.	Teresa Deese (b) (4)	04 Mar 2021 16:29:20
User entered 'pellets' reason for change: Data Entry Error	Teresa Deese (b) (4)	04 Mar 2021 16:29:20
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:07
DataPoint Un-verified.	Teresa Deese (b) (4)	26 Jan 2021 15:54:18
User entered empty; reason for change Data Entry Error	Teresa Deese (b) (4)	26 Jan 2021 15:54:18
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:12:26
User entered 'pouch' reason for change: Data Entry Error	zackery harmon (b) (4)	02 Dec 2020 22:25:39
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:19:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Unknown'	Tiffany Jewell (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'other (OTHER)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Every 3 months'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:39:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User closed query 'please verify route in source' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 15:46:15
Query 'please verify route in source' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	12 Mar 2021 21:07:31
User opened query 'please verify route in source' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:24:50
DataPoint Un-verified.	Teresa Deese (b) (4)	04 Mar 2021 16:29:20
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Teresa Deese (b) (4)	04 Mar 2021 16:29:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Other (OTHER)'	Tiffany Jewell (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:24:56
DataPoint Un-verified.	Teresa Deese (b) (4)	04 Mar 2021 16:29:20
User entered empty; reason for change Data Entry Error	Teresa Deese (b) (4)	04 Mar 2021 16:29:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Unknown'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'UN UNK 2014'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User entered empty.	System	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User entered empty.	System	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:34
User entered empty.	System	31 Aug 2020 12:48:47

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:33:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:33:22
Data point term sent to Coder	System	23 Oct 2020 19:24:01
User entered 'flu vac'	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Yes (Y)'	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'flu prevention'	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered '0.5'	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'mL (mL)'	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'once (ONCE)'	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'Intramuscular (INTRAMUSCULAR)'	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered empty.	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered '18 Oct 2020'	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered '0'	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'No (N)'	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered '18 Oct 2020'	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:14
User entered 'No (N)'	Teresa Deese (b) (4)	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:23:04

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 22:02:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 22:02:13
Data point term sent to Coder	System	11 Feb 2021 22:01:55
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 01:05:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 01:05:48
Data point term sent to Coder	System	22 Dec 2020 21:53:29
User entered 'OXYBUTYNIN'	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered 'PROPHYLAXIS OF BLADDER SPASMS POST-PROSTATECTOMY'	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered '5'	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered empty.	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered 'three times daily (TID)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered empty.	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered empty.	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered '17 Dec 2020'	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered '0'	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:17:20
DataPoint Un-verified.	Teresa Deese (b) (4)	11 Feb 2021 22:02:06
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	11 Feb 2021 22:02:06
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:31:02
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:56
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:17:21
User closed query 'source = end date, 20Dec20, please verify' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 14:17:18
User entered '20 Dec 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	11 Feb 2021 22:02:06
Query 'source = end date, 20Dec20, please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	11 Feb 2021 22:01:25
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
User opened query 'source = end date, 20Dec20, please verify' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:25:16
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:58
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered empty.	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered 'No (N)'	Erica Osmundsen (b) (4)	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
User entered '3'	System	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
User entered 'I'	System	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:39
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:15
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	11 Feb 2021 22:01:00
User entered '804 (804)'	System	22 Dec 2020 21:53:09
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	22 Dec 2020 21:50:49
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	23 Oct 2020 19:23:54

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: CEPHALEXIN [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 00:47:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 00:47:40
Data point term sent to Coder	System	08 Feb 2021 14:41:02
Coding entries removed.	Erica Osmundsen (b) (4)	08 Feb 2021 14:40:02
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:31:24
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: CEPHALEXIN [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 07:32:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 07:32:02
Data point term sent to Coder	System	25 Jan 2021 21:30:49
User entered 'cephalexin'	Lilian Nukuna (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:31:27
User entered 'No (N)'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User closed query 'source = laceration, please verify' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:25:42
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
Query 'source = laceration, please verify' answered with 'updated per source' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:40:33
User entered 'laceration to both hands' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Feb 2021 14:40:02
User opened query 'source = laceration, please verify' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:31:21
User entered 'wound healing'	Lilian Nukuna (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:31:47
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 19:31:41
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:31:31
User entered '500'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:31:43
User entered 'mg (mg)'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:31:50
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User closed query 'please verify source documentation' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:26:04
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
Query 'please verify source documentation' answered with 'clarified in source document' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:41:04
User opened query 'please verify source documentation' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:32:23
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:06
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:31:52
User entered 'twice daily (BID)'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:25
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:27
User entered 'Oral (ORAL)'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:29
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:31
User entered '14 Jan 2021'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:33
User entered '0'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Feb 2021 14:41:19
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User closed query 'source = end date, 24Jan2020, please verify' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:26:14
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
Query 'source = end date, 24Jan2020, please verify' answered with 'done' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:41:23
User entered '24 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Feb 2021 14:41:19
User opened query 'source = end date, 24Jan2020, please verify' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:32:56
User entered empty.	Lilian Nukuna (b) (4)	25 Jan 2021 21:30:48
	(b) (4)	

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered 'No (N)'	Lilian Nukuna (b) (4) (b) (4)	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User entered '2'	System	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User entered '1'	System	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:51
User entered '804 (804)'	System	25 Jan 2021 21:30:48

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:40:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 13:00:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 13:00:07
Data point term sent to Coder	System	26 Jan 2021 16:01:40
User entered 'docusate'	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:40:24
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:40:22
User entered 'prevent constipation post op'	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:40:20
User entered '100'	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:40:18
User entered 'mg (mg)'	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:40:17
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:40:13
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:40:11
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:40:09
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:40:05
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:57:58
Query 'please verify source for start date as medication is listed as D/C med on 18Dec2020. ' canceled (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 18:57:56
User opened query 'please verify source for start date as medication is listed as D/C med on 18Dec2020. ' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 18:24:17
User entered '17 Dec 2020'	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:58:00
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:40:02
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Jan 2021 16:03:08
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User closed query 'please verify as D/C date 18Dec and prescription was x 5. Please reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:26:38
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
Query 'please verify as D/C date 18Dec and prescription was x 5. Please reconcile.' answered with 'last used on this date per patient' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:52:03
User opened query 'please verify as D/C date 18Dec and prescription was x 5. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 18:58:46
User entered '20 Dec 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Jan 2021 16:03:08
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:40:33
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User entered empty.	System	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User entered empty.	System	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:55:56
User entered empty.	System	26 Jan 2021 16:01:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 14:55:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	08 Feb 2021 14:55:37
Data point term sent to Coder	System	08 Feb 2021 14:55:13
Coding entries removed.	Erica Osmundsen (b) (4)	08 Feb 2021 14:54:35
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:00:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 00:22:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	27 Jan 2021 00:22:59
Data point term sent to Coder	System	26 Jan 2021 16:04:47
User entered 'percocet'	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User closed query 'please verify as indication is "treatment" of post op pain' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:27:37
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
Query 'please verify as indication is "treatment" of post op pain' answered with 'done' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:54:39
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Feb 2021 14:54:35
User opened query 'please verify as indication is "treatment" of post op pain' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:01:15
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 19:00:38
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:00:36
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered 'POST OP PAIN' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Feb 2021 14:54:35
User entered 'prevent post op pain'	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:00:48
User entered '5/325'	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:00:50
User entered 'mg (mg)'	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:00:53
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
Query 'per source , every 4 hours as needed. Please verify' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:27:44
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
User opened query 'per source , every 4 hours as needed. Please verify' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:01:55
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:01:31
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:01:59
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:02:01
User entered '17 Dec 2020'	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:02:03
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:02:05
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered '20 Dec 2020'	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:02:08
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User entered empty.	System	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User entered empty.	System	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:08
User entered empty.	System	26 Jan 2021 16:04:15

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:02:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 16:06:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 16:06:55
Data point term sent to Coder	System	26 Jan 2021 16:05:48
User entered 'bactrim DS'	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:02:51
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:02:53
User entered 'prevent post op infection'	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:02:56
User entered '800/160'	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:02:59
User entered 'mg (mg)'	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:01
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:03
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:05
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:08
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:10
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:12
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	26 Jan 2021 16:05:36
User entered '17 Dec 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Jan 2021 16:05:36
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	26 Jan 2021 16:05:28
User entered '17 Dec 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Jan 2021 16:05:28
User entered '17 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:13
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:15
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:36
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	26 Jan 2021 16:05:36
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	26 Jan 2021 16:05:08
User entered '20 Dec 2020'	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:18
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User entered '2'	System	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User entered '1'	System	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:13
User entered '804 (804)'	System	26 Jan 2021 16:05:08

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN, PRODUCTSYNONYM: AMOXIL [AMOXICILLIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 23:55:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 23:55:54
Data point term sent to Coder	System	26 Jan 2021 16:06:49
User entered 'amoxil'	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:43
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:44
User entered 'strep infection- throat``'	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:46
User entered '875'	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:47
User entered 'mg (mg)'	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:50
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:52
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:54
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:55
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:58
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:04:00
User entered '28 Dec 2020'	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:04:02
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:04:04
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:04:06
User entered '6 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:04:08
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User entered '2'	System	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User entered '1'	System	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:18
User entered '804 (804)'	System	26 Jan 2021 16:06:36

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:08:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 16:08:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 16:08:50
Data point term sent to Coder	System	26 Jan 2021 16:07:51
User entered 'losartan'	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:08:22
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
User closed query 'per previous medical history this is a new condition but is not listed as an AE or MAAE, please reconcile' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:28:44
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
Query 'per previous medical history this is a new condition but is not listed as an AE or MAAE, please reconcile' answered with 'added to medical history, not previously reported' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:55:23
User opened query 'per previous medical history this is a new condition but is not listed as an AE or MAAE, please reconcile' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:08:03
User entered 'borderline hypertension'	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:08:46
User entered '50'	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:08:49
User entered 'mg (mg)'	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:08:51
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:08:53
User entered 'once daily (QD)'	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:08:54
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:08:59
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:09:01
User entered empty.	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:18:49
User closed query 'source = Nov, 2020, please verify' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 14:18:47
Query 'source = Nov, 2020, please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	11 Feb 2021 22:02:59
User opened query 'source = Nov, 2020, please verify' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:29:30
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:29:12
User closed query 'please verify documentation of where this information was obtained as there is no source note. ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:29:03
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:36
Query 'please verify documentation of where this information was obtained as there is no source note. ' answered with 'updated information clarified with subject' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 14:55:46
User entered 'UN UNK 2018' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Feb 2021 14:55:35
User opened query 'please verify documentation of where this information was obtained as there is no source note. ' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:12:12
User entered 'UN Nov 2020'	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:36
User entered '0'	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:09:04
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:09:05
User entered '14 Jan 2021'	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:09:07
User entered 'No (N)'	Teresa Deese (b) (4)	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User entered '1'	System	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User entered '1'	System	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:24
User entered '804 (804)'	System	26 Jan 2021 16:07:46

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:08
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)	14 Apr 2021 19:18:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 19:18:01
Data point term sent to Coder	System	14 Apr 2021 19:15:08
User entered 'TRAMADOL'	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:09
User entered 'No (N)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:11
User entered 'RIGHT KNEE PAIN'	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:13
User entered '50'	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:15
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:16
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:18
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:20
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:21
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:23
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:25
User entered '07 Apr 2021'	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:26
User entered '0'	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:28
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:30
User entered empty.	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:21:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:41:31
User entered 'No (N)'	Erica Osmundsen (b) (4)	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 19:14:44

US3202304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:45:32

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:18:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:25
User entered 'No (N)'	Tiffany Jewell (b) (4)	31 Aug 2020 12:49:06

US3202304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:45:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:19:54
User entered '17 Dec 2020'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:54

US3202304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:45:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:18:36
User closed query 'Hospital notes= Complete Laser Enucleation of Prostate, please verify' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:18:34
Query 'Hospital notes= Complete Laser Enucleation of Prostate, please verify' answered with 'done' (Site from CRA).	Erica Osmundsen (b) (4)	08 Feb 2021 15:01:09
User entered 'PROSTATECTOMY complete laser enucleation of prostate' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Feb 2021 15:01:05
User opened query 'Hospital notes= Complete Laser Enucleation of Prostate, please verify' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 18:19:52
User entered 'PROSTATECTOMY'	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:54

US3202304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:45:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:19:58
User entered 'Adverse Event (AE)'	Erica Osmundsen (b) (4) 	22 Dec 2020 21:48:54

US3202304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:45:32

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:20:00
User entered empty.	Erica Osmundsen (b) (4)	22 Dec 2020 21:48:54

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'USA-US128-2020-MRNA-1273-P301000015'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Yes (Y)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Yes (Y)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Mark'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'McKenzie'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'US'	System	23 Dec 2020 14:36:32

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Feb 2021 16:34:14
User entered '3'	System	09 Feb 2021 13:05:49
User entered '2'	System	27 Jan 2021 17:34:34
User entered '1'	System	23 Dec 2020 14:36:32

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'USA-US128-2020-MRNA-1273-P301000015'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Yes (Y)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Yes (Y)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Mark'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'McKenzie'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'US'	System	23 Dec 2020 14:36:32

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Feb 2021 16:34:14
User entered '3'	System	09 Feb 2021 13:05:49
User entered '2'	System	27 Jan 2021 17:34:34
User entered '1'	System	23 Dec 2020 14:36:32

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:45:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
User entered '23/Dec/2020 09:36'	System	23 Dec 2020 14:36:32

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:45:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:36:37
User entered 'I'	(b) (4), (b) (6)	23 Dec 2020 14:36:32

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'USA-US128-2020-MRNA-1273-P301000015'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Yes (Y)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Yes (Y)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Mark'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'McKenzie'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'US'	System	23 Dec 2020 14:36:32

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Feb 2021 16:34:14
User entered '3'	System	09 Feb 2021 13:05:49
User entered '2'	System	27 Jan 2021 17:34:34
User entered '1'	System	23 Dec 2020 14:36:32

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:45:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
User entered '27/Jan/2021 12:34'	System	27 Jan 2021 17:34:34

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:45:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:05:40
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:18:40
User entered 'I'	(b) (4), (b) (6)	27 Jan 2021 17:34:34

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'USA-US128-2020-MRNA-1273-P301000015'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Yes (Y)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Yes (Y)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Mark'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'McKenzie'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'US'	System	23 Dec 2020 14:36:32

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Feb 2021 16:34:14
User entered '3'	System	09 Feb 2021 13:05:49
User entered '2'	System	27 Jan 2021 17:34:34
User entered '1'	System	23 Dec 2020 14:36:32

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:45:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:16:28
User entered '09/Feb/2021 13:05'	System	09 Feb 2021 13:05:49

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:45:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:34:00
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 14:16:28
User entered 'I'	(b) (4), (b) (6)	09 Feb 2021 13:05:49

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'USA-US128-2020-MRNA-1273-P301000015'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Yes (Y)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Yes (Y)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'No (N)'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'Mark'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'McKenzie'	System	23 Dec 2020 14:28:13

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:18:40
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 17:34:19
User entered 'US'	System	23 Dec 2020 14:36:32

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Feb 2021 16:34:14
User entered '3'	System	09 Feb 2021 13:05:49
User entered '2'	System	27 Jan 2021 17:34:34
User entered '1'	System	23 Dec 2020 14:36:32

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:45:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:33:31
User entered '12/Feb/2021 11:34'	System	12 Feb 2021 16:34:14

US3202304

Folder: SAE USA-US128-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:45:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:00:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:33:31
User entered 'I'	(b) (4), (b) (6)	12 Feb 2021 16:34:14