

US3192006 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:39:06

All time stamps listed in this document are displayed in GMT

US3192006

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 19:35:14

Generated On: 09 Jun 2021 15:39:06

[Participant ID](#)

US3192006

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

US3192006

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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 19:18:00

Generated On: 09 Jun 2021 15:39:06

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
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 19:18:00

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 19:18:00

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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 19:18:00

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 19:18:00

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Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	20 APR 2012
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)	APR 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Condition	HYPERTENSION
Start date (dd MMM yyyy)	20 APR 2012
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)	APR 2012
Start Year (derived)	2012
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 19:18:00

Generated On: 09 Jun 2021 15:39:06

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	20 APR 2012
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)	APR 2012
Start Year (derived)	2012
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 19:18:00

Generated On: 09 Jun 2021 15:39:06

Condition	LOW TESTOSTERONE
Start date (dd MMM yyyy)	20 APR 2012
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)	APR 2012
Start Year (derived)	2012
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 19:18:00

Generated On: 09 Jun 2021 15:39:06

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	20 APR 2012
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)	APR 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Condition	CHRONIC KIDNEY DISEASE
Start date (dd MMM yyyy)	14 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:08 (24 HR)
Vital Signs Date and Time (derived)	1 AUG 2020 13:08
Height (<i>xxx.x</i>)	69.5 in
Weight (<i>xxx.x</i>)	218.6 lb
BMI (<i>xxx.x</i>)	31.88529 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 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 19:18:00

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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 19:18:00

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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 19:18:00

Generated On: 09 Jun 2021 15:39:06

What was the date of randomization? (dd MMM yyyy) 01 AUG 2020

What was the participant's randomization number? 184405

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Mar 2021 18:33:20

Generated On: 09 Jun 2021 15:39:06

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) 28 Mar 2021 18:33:20

Generated On: 09 Jun 2021 15:39:06

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)	1 AUG 2020
Time of assessment (00:00-23:59)	13:08 (24 HR)
Vital Signs Date and Time (derived)	1 AUG 2020 13:08
Temperature (xxx.x)	97 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Mar 2021 18:33:20

Generated On: 09 Jun 2021 15:39:06

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 AUG 2020
Time of assessment (00:00-23:59)	14:42 (24 HR)
Vital Signs Date and Time (derived)	1 AUG 2020 14:42
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 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 19:18:00

Generated On: 09 Jun 2021 15:39:06

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 19:18:00

Generated On: 09 Jun 2021 15:39:06

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) 1 AUG 2020

What was the treatment time? (00:00-23:59) 13:39 (24 HR)

Treatment Date and Time (derived) 1 AUG 2020 13:39

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 19:18:00

Generated On: 09 Jun 2021 15:39:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 AUG 2020
Collection time (00:00-23:59)	13:25 (24 HR)
Collection date and time (derived)	1 AUG 2020 13:25

US3192006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

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 15:39:06

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

01 AUG 2020 14:26

PC Open Date & Time

01 AUG 2020 13:59

PC Close Date & Time

01 AUG 2020 16:29

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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 95.8 °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 AUG 2020 17:51
PC Open Date & Time	01 AUG 2020 17:24
PC Close Date & Time	02 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

96.9 °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

02 AUG 2020 12:01

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 14:17

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

04 AUG 2020 15:29

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 12:34

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 13:59

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

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

96.8 °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

07 AUG 2020 15:45

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 14:27

PC Open Date & Time

01 AUG 2020 13:59

PC Close Date & Time

01 AUG 2020 16:29

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

01 AUG 2020 17:52

PC Open Date & Time

01 AUG 2020 17:24

PC Close Date & Time

02 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

02 AUG 2020 12:01

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

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

03 AUG 2020 14:17

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

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

04 AUG 2020 15:30

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

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

05 AUG 2020 12:34

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

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

06 AUG 2020 13:59

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

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

07 AUG 2020 15:45

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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

No ☒

Yes ☐

PC Time stamp	01 AUG 2020 14:28
PC Open Date & Time	01 AUG 2020 13:59
PC Close Date & Time	01 AUG 2020 16:29

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

No ☒

Yes ☐

PC Time stamp	01 AUG 2020 17:53
PC Open Date & Time	01 AUG 2020 17:24
PC Close Date & Time	02 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

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 ☒

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 14:18
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

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 ☒

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EAB) (1725)

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US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 15:30
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

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

53 of 2338

EAB) (1725)

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 12:34
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 13:59
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

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 ☒

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 15:45
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3192006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192006

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192006

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192006

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	VISIT2

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 14:40
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 16:00
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3192006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 AUG 2020

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

US3192006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 29 AUG 2020

What was the treatment time? (00:00-23:59) 15:26 (24 HR)

Treatment Date and Time (derived) 29 AUG 2020 15:26

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

US3192006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

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

Collection date (dd MMM yyyy)	29 AUG 2020
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Collection time (00:00-23:59)	15:12 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	29 AUG 2020 15:12
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US3192006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

Collection date (dd MMM yyyy)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:10	29 AUG 2020 15:10
Nasopharyngeal Swab 2	No		

US3192006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

29 AUG 2020 15:58

PC Open Date & Time

29 AUG 2020 15:46

PC Close Date & Time

29 AUG 2020 18:16

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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 96.8 °F

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

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

PC Time Stamp	29 AUG 2020 21:16
PC Open Date & Time	29 AUG 2020 19:11
PC Close Date & Time	30 AUG 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:00

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

01 SEP 2020 19:15

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

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

97.0 °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

02 SEP 2020 19:43

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:36

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 18:00

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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

29 AUG 2020 15:59

PC Open Date & Time

29 AUG 2020 15:46

PC Close Date & Time

29 AUG 2020 18:16

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 21:17

PC Open Date & Time

29 AUG 2020 19:11

PC Close Date & Time

30 AUG 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

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

31 AUG 2020 12:01

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

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

01 SEP 2020 19:15

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

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

02 SEP 2020 19:43

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

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

03 SEP 2020 12:37

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

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

04 SEP 2020 18:00

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 16:00
PC Open Date & Time	29 AUG 2020 15:46
PC Close Date & Time	29 AUG 2020 18:16

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 21:17
PC Open Date & Time	29 AUG 2020 19:11
PC Close Date & Time	30 AUG 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

Yes ☐

PC Time stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

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)

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US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 19:16
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

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 ☒

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EAB) (1725)

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 19:44
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:37
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

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 ☒

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 18:01
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3192006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192006

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192006

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192006

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:18:00

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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	VISIT3

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	08:10 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:10
Temperature (xxx.x)	96.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3192006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

08:25 (24 HR)

Collection date and time (derived)

28 SEP 2020 08:25

US3192006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 19:18:01

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 OCT 2020 10:01:11

Patient Cloud Open Date & Time

01 OCT 2020 00:01

Patient Cloud Close Date & Time

05 OCT 2020 23:59

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 OCT 2020 19:48:13

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 OCT 2020 12:50:34

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 OCT 2020 12:44:57

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 15:20:04

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 06:40:42

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT	DAY 113
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"/>

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 12:50:10

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 13:40:10

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

08 DEC 2020 18:25:31

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

14 DEC 2020 07:21:37

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

21 DEC 2020 08:33:39

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 07:29:57

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

05 JAN 2021 16:57:25

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

11 JAN 2021 00:39:08

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

21 JAN 2021 17:59:55

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

25 JAN 2021 06:58:06

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

01 FEB 2021 08:13:13

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

11 FEB 2021 18:00:59

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 17:59:38

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

22 FEB 2021 07:23:45

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 14:54:22

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 12:00:36

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

15 MAR 2021 07:10:00

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

29 MAR 2021 07:37:54

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

05 APR 2021 07:02:09

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 08:20:01

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 16:42:35

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 12:00:49

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 09:32:14
Patient Cloud Open Date & Time	03 MAY 2021 00:01
Patient Cloud Close Date & Time	07 MAY 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUN 2021 00:01
Patient Cloud Close Date & Time	11 JUN 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2021 00:01
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Patient Cloud Close Date & Time	09 JUL 2021 23:59
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US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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°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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 SEP 2021 00:01
Patient Cloud Close Date & Time	17 SEP 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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°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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 <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"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 467

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

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

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

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

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

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

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	19 NOV 2021 23:59
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US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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="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"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	10 DEC 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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°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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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°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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 APR 2022 00:01
Patient Cloud Close Date & Time	29 APR 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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°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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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"/>

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

Date and time of submission

Patient Cloud Open Date & Time	03 OCT 2022 00:01
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Patient Cloud Close Date & Time	07 OCT 2022 23:59
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US3192006

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:39:06

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		01 MAR 2021 14:54:52

US3192006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:15

Generated On: 09 Jun 2021 15:39:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192006

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:15

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:15

Generated On: 09 Jun 2021 15:39:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192006

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:15

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:15

Generated On: 09 Jun 2021 15:39:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192006

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:15

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:15

Generated On: 09 Jun 2021 15:39:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192006

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:15

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 MAR 2021
Time of assessment (00:00-23:59)	15:11 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 15:11
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192006

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 MAR 2021

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

US3192006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 MAR 2021
Collection time (00:00-23:59)	15:16 (24 HR)
Collection date and time (derived)	2 MAR 2021 15:16

US3192006

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192006

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192006

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3192006

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:39:06

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"/>

US3192006

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:39:06

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3192006

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3192006

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

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 14:17:07

Generated On: 09 Jun 2021 15:39:06

Date of updated informed consent (*dd MMM yyyy*) 6 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 7 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3192006

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 JAN 2021

Collection time (00:00-23:59)

16:10 (24 HR)

Collection date and time (derived)

6 JAN 2021 16:10

US3192006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 JAN 2021
Collection time (00:00 - 23:59)	16:15
Collection Date and Time (derived)	06 JAN 2021 16:15

US3192006

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 19:35:14

Generated On: 09 Jun 2021 15:39:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Mar 2021 17:07:39

Generated On: 09 Jun 2021 15:39:06

AEID	USA-US097-2020-MRNA-1273-P30 1000001
Adverse event	DEHYDRATION
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)	16 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	17 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Mar 2021 17:07:39

Generated On: 09 Jun 2021 15:39:06

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	

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Mar 2021 17:07:39

Generated On: 09 Jun 2021 15:39:06

PATIENT WAS GOLFING IN 100
DEGREE TEMPERATURE AND
BECAME DIZZY FOLLOWED BY
BRIEF LOC. TAKEN TO
HOSPITAL AND ADMITTED FOR
DEHYDRATION AND
HYPOTENSION. LISINOPRIL
40MG QD TAKEN SINCE 2012
WAS DECREASED TO 20MG QD.
HOSPITAL RECORDS
REQUESTED AND PENDING AT
TIME OF REPORT. PT WAS
DISCHARGED HOME W/O
SEQUELAE ON 17AUG2020.
HIS TEMP WAS 97.6AND 1LITER
OF FLUIDS

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Mar 2021 17:07:39

Generated On: 09 Jun 2021 15:39:06

AEID	USA-US097-2020-MRNA-1273-P30 1000001
Adverse event	HYPOTENSION
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)	16 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	17 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Mar 2021 17:07:39

Generated On: 09 Jun 2021 15:39:06

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	

US3192006

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Mar 2021 17:07:39

Generated On: 09 Jun 2021 15:39:06

PATIENT WAS GOLFING IN 100
DEGREE TEMPERATURE AND
BECAME DIZZY FOLLOWED BY
BRIEF LOC. TAKEN TO
HOSPITAL AND ADMITTED FOR
DEHYDRATION AND
HYPOTENSION. LISINOPRIL
40MG QD TAKEN SINCE 2012
WAS DECREASED TO 20MG QD.
HOSPITAL RECORDS
REQUESTED AND PENDING AT
TIME OF REPORT. PT WAS
DISCHARGED HOME W/O
SEQUELAE ON 17AUG2020.

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Mar 2021 17:07:39

Generated On: 09 Jun 2021 15:39:06

AEID	USA-US097-2020-MRNA-1273-P30 1000001
Adverse event	WORSENING CHRONIC KIDNEY DISEASE
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)	16 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	17 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Mar 2021 17:07:39

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

Form: Adverse Events (4)

Data signed: (b) (4) 20 Mar 2021 17:07:39

Generated On: 09 Jun 2021 15:39:06

AEID	USA-US097-2020-MRNA-1273-P30 1000001
Adverse event	HYPERKALEMIA
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)	16 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	17 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Mar 2021 17:07:39

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	
DUE TO DEHYDRATION, PATIENT WAS DIAGNOSED WITH HYPERKALEMIA WHILE IN HOSPITAL.	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 20 Feb 2021 19:35:14

Generated On: 09 Jun 2021 15:39:06

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

Yes ☒

No ☐

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

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication TESTOSTERONE CYPIONATE

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

	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)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication PREVENTATIVE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 AUG 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 (4)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (5)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 AUG 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 (6)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS II

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication PREVENTATIVE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication PREVENTATIVE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication GLUCOSAMINE

Prophylaxis Yes ☐
No ☒

Indication PREVENTATIVE

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication CHRONDROITIN/MSM
COMPLEX

Prophylaxis Yes ☒
No ☐

Indication PREVENTATIVE

Dose per administration 1103

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

	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)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

	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)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input 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"/>

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication LOVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

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

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication DEHYDRATION

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

EVERY HOUR

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 AUG 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"/>

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication GLUCAGON

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
HYPOGLYCEMIA

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

PER HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	16 AUG 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"/>

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication GLUCOSE INFUSION

Prophylaxis Yes ☐
No ☒

Indication HYPERKALEMIA

Dose per administration 12.5

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 (15)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	16 AUG 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"/>

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

Name of Medication ONDANSETRON

Prophylaxis Yes ☒
No ☐

Indication PROPHYLACTIC FOR
NAUSEA/VOMITING

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 Apr 2021 13:46:20

Generated On: 09 Jun 2021 15:39:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 AUG 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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Feb 2021 19:35:14

Generated On: 09 Jun 2021 15:39:06

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:39:06

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3192006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:39:06

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 ☐

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	31/AUG/2020 11:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	09/SEP/2020 13:51
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

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	25/SEP/2020 14:38
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

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	28/SEP/2020 15:02
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

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	12/OCT/2020 13:09
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

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	11/NOV/2020 19:26
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

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	23/NOV/2020 15:05
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

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	08/DEC/2020 20:48
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

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	07/JAN/2021 16:38
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

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	21/JAN/2021 15:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	03/MAR/2021 10:39
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

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Data signed: (b) (4) 03 Apr 2021 13:46:21

Generated On: 09 Jun 2021 15:39:06

SAEID	USA-US097-2020-MRNA-1273-P301000001
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	16/MAR/2021 11:08
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

US3192006 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

US3192006

Form: Participant Creation

Generated On: 09 Jun 2021 15:39:06

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:01:08
User entered 'US3192006'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 19:39:06

US3192006

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:09:43
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:17:40

US3192006

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:09:43
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 19:39:07

US3192006

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[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 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:09:43
User entered 'Clinic (Clinic)'	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:17:40

US3192006

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'SCRN'	System	01 Aug 2020 21:17:40

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered (b) (6) 1951'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 19:39:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered '69'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'YEARS'	System	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered '69'	System	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered 'Male (M)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered 'I'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered empty.	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:06

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:13:08
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:17:08

US3192006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:14:46
User entered '1 Aug 2020'	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'Aug 2020'	System	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered '2020'	System	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:06

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:14:46
User entered 'Amendment 1 (1)'	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:14:46
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:14:46
User entered empty.	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:14:46
User entered empty.	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
DataPoint Verified.		18 Feb 2021 20:39:55
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:14:48
DataPoint Verified.		07 Aug 2020 18:14:46
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:14:46
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 19:39:07

US3192006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'I'	System	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:15:10
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:17:48

US3192006

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:39:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:15:26
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:28:51

US3192006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:10:22
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).		10 Sep 2020 20:07:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 02:44:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 02:44:37
Data point term sent to Coder	System	09 Sep 2020 02:43:30
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'updated' (Site from DM).	Yvonne De Los Reyes (b) (4)	09 Sep 2020 02:43:29
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 02:43:24
Coding entries removed.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 02:43:24
User entered 'Type II Diabetes' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	09 Sep 2020 02:43:24
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 11:05:43
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:16:11

US3192006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	02 Aug 2020 01:31:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Aug 2020 01:31:01
Data point term sent to Coder	System	02 Aug 2020 01:30:29
User entered 'Diabetes Type II'	Tianna Young (b) (4)	02 Aug 2020 01:30:05

US3192006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:11
User entered '20 Apr 2012'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:30:05

US3192006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:11
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:30:05

US3192006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:11
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:30:05

US3192006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:11
User entered empty.	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:30:05

US3192006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:11
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:30:05

US3192006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'Apr 2012'	System	02 Aug 2020 01:30:05

US3192006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered '2012'	System	02 Aug 2020 01:30:05

US3192006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered empty.	System	02 Aug 2020 01:30:05

US3192006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered empty.	System	02 Aug 2020 01:30:05

US3192006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:08:41
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'updated' (Site from DM).	Yvonne De Los Reyes (b) (4)	09 Sep 2020 02:43:54
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 11:05:54
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:16:16
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 01:33:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 01:33:01
Data point term sent to Coder	System	02 Aug 2020 01:31:30
User entered 'Hypertension'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:30:47

US3192006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:16
User entered '20 Apr 2012'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:30:47

US3192006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:16
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:30:47

US3192006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:16
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:30:47

US3192006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:16
User entered empty.	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:30:47

US3192006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:16
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:30:47

US3192006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'Apr 2012'	System	02 Aug 2020 01:30:47

US3192006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered '2012'	System	02 Aug 2020 01:30:47

US3192006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered empty.	System	02 Aug 2020 01:30:47

US3192006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered empty.	System	02 Aug 2020 01:30:47

US3192006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 01:43:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 01:43:02
Data point term sent to Coder	System	02 Aug 2020 01:42:31
User entered 'Hyperlipidemia'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:42:28

US3192006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered '20 Apr 2012'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:42:28

US3192006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:42:28

US3192006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:42:28

US3192006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered empty.	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:42:28

US3192006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:42:28

US3192006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'Apr 2012'	System	02 Aug 2020 01:42:28

US3192006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered '2012'	System	02 Aug 2020 01:42:28

US3192006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered empty.	System	02 Aug 2020 01:42:28

US3192006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered empty.	System	02 Aug 2020 01:42:28

US3192006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 01:44:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 01:44:02
Data point term sent to Coder	System	02 Aug 2020 01:43:32
User entered 'Low testosterone'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:43:19

US3192006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered '20 Apr 2012'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:43:19

US3192006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:43:19

US3192006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:43:19

US3192006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered empty.	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:43:19

US3192006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:43:19

US3192006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'Apr 2012'	System	02 Aug 2020 01:43:19

US3192006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered '2012'	System	02 Aug 2020 01:43:19

US3192006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered empty.	System	02 Aug 2020 01:43:19

US3192006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered empty.	System	02 Aug 2020 01:43:19

US3192006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:09:53
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).		10 Sep 2020 20:08:58
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 02:45:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 02:45:41
Data point term sent to Coder	System	09 Sep 2020 02:44:33
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 02:44:14
Coding entries removed.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 02:44:14
User entered 'HYPOTHYROIDISM' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	09 Sep 2020 02:44:14
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'updated' (Site from DM).	Yvonne De Los Reyes (b) (4)	09 Sep 2020 02:44:04
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 11:06:09
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:16:24
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 01:46:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	02 Aug 2020 01:46:02
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	02 Aug 2020 01:44:33
User entered 'Hypothyroid'	Tianna Young (b) (4)	02 Aug 2020 01:43:51
	(b) (4)	

US3192006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered '20 Apr 2012'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:43:51

US3192006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:43:51

US3192006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:43:51

US3192006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered empty.	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:43:51

US3192006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:16:24
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:43:51

US3192006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'Apr 2012'	System	02 Aug 2020 01:43:51

US3192006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered '2012'	System	02 Aug 2020 01:43:51

US3192006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered empty.	System	02 Aug 2020 01:43:51

US3192006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered empty.	System	02 Aug 2020 01:43:51

US3192006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:39:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:09:43
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 01:48:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 01:48:15
Data point term sent to Coder	System	21 Jan 2021 01:46:53
User entered 'Chronic Kidney Disease'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:45:52

US3192006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:09:43
User entered '14 Jul 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:45:52

US3192006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:09:43
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:45:52

US3192006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:39:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:09:43
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:45:52

US3192006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:09:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:45:52

US3192006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:39:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:09:43
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:45:52

US3192006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'Jul 2020'	System	21 Jan 2021 01:45:52

US3192006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered '2020'	System	21 Jan 2021 01:45:52

US3192006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered empty.	System	21 Jan 2021 01:45:52

US3192006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered empty.	System	21 Jan 2021 01:45:52

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:17:33
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:18:58

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:17:33
User entered '1 Aug 2020'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:18:58

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:17:33
User entered '13:08'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:18:58

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered '1 Aug 2020 13:08'	System	02 Aug 2020 01:18:58

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:17:33
User entered '69.5' in	Tianna Young (b) (4)	02 Aug 2020 01:18:58
DataPoint set to visible.	(b) (4) System	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:17:33
User entered '218.6' lb	Tianna Young (b) (4)	02 Aug 2020 01:18:58
DataPoint set to visible.	(b) (4) System	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
Amendment Manager: User entered '31.88529'	System	16 Sep 2020 23:40:37
User entered '31.9'	System	02 Aug 2020 01:18:58
DataPoint set to visible.	System	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'kg/m2'	System	02 Aug 2020 01:18:58
DataPoint set to visible.	System	01 Aug 2020 21:18:06

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
DataPoint Verified.		18 Feb 2021 20:40:11
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 16:06:00
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.	(b) (4), (b) (6)	02 Sep 2020 04:02:06
NOTE: Route is not required ' (Site from DM).		
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.	Cynthia Montgomery	01 Sep 2020 16:33:58
NOTE: Route is not required ' answered with 'reconciled' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Cynthia Montgomery	01 Sep 2020 16:33:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Sep 2020 16:33:44
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.	(b) (4), (b) (6)	31 Aug 2020 17:43:17
NOTE: Route is not required ' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:17:33
User entered '97' F	Tianna Young (b) (4)	02 Aug 2020 01:18:58
	(b) (4)	

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
DataPoint Verified.		18 Feb 2021 20:40:11
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Un-verified.	(b) (4)	
	Cynthia Montgomery	01 Sep 2020 16:33:44
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cynthia Montgomery	01 Sep 2020 16:33:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:17:33
User entered 'Other (Other)'	Tianna Young (b) (4)	02 Aug 2020 01:18:58
	(b) (4)	

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
DataPoint Verified.		18 Feb 2021 20:40:11
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Un-verified.	(b) (4)	
	Cynthia Montgomery	01 Sep 2020 16:33:44
User entered empty; reason for change Data Entry Error	(b) (4)	01 Sep 2020 16:33:44
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:17:33
User entered 'Temporal'	Tianna Young (b) (4)	02 Aug 2020 01:18:58
	(b) (4)	

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
DataPoint Verified.		18 Feb 2021 20:40:11
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Un-verified.	(b) (4)	
	Cynthia Montgomery	01 Sep 2020 16:33:44
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery	01 Sep 2020 16:33:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:17:33
User entered '82'	Tianna Young (b) (4)	02 Aug 2020 01:18:58
	(b) (4)	

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'bpm'	System	02 Aug 2020 01:18:58

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
DataPoint Verified.		18 Feb 2021 20:40:11
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Un-verified.	(b) (4)	
	Cynthia Montgomery	01 Sep 2020 16:33:44
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery	01 Sep 2020 16:33:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:17:33
User entered '16'	Tianna Young (b) (4)	02 Aug 2020 01:18:58
	(b) (4)	

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'breaths/min'	System	02 Aug 2020 01:18:58

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
DataPoint Verified.		18 Feb 2021 20:40:11
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Un-verified.	(b) (4)	
	Cynthia Montgomery	01 Sep 2020 16:33:44
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery	01 Sep 2020 16:33:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:17:33
User entered '120'	Tianna Young (b) (4)	02 Aug 2020 01:18:58
	(b) (4)	

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'mmHg'	System	02 Aug 2020 01:18:58

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
DataPoint Verified.		18 Feb 2021 20:40:11
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Un-verified.	(b) (4)	
	Cynthia Montgomery	01 Sep 2020 16:33:44
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery	01 Sep 2020 16:33:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:17:33
User entered '69'	Tianna Young (b) (4)	02 Aug 2020 01:18:58
	(b) (4)	

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User entered 'mmHg'	System	02 Aug 2020 01:18:58

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07

US3192006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07

US3192006

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:17:58
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:28:04

US3192006

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 10:48:11
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	29 Aug 2020 23:58:02
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:17:58
User entered '1 Aug 2020'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:28:04

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered empty.	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered '0'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered 'l'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
User entered '0'	Tianna Young (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:05:07
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:03
User entered empty.	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:27:31

US3192006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:24
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:24:30

US3192006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:24
User entered '1 Aug 2020'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:24:30

US3192006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:24
User entered 'Clinic (Clinic)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:24:30

US3192006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'VISIT1'	System	02 Aug 2020 01:24:30

US3192006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:33
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 20:34:07

US3192006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:06

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.		18 Feb 2021 20:40:23
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
	System	21 Aug 2020 01:39:09
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:39:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 20:34:07
User entered '184405' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 20:34:07

US3192006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:06

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:32
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 20:34:07

US3192006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:06

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)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:43
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:26:15

US3192006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:06

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)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:45
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:26:15

US3192006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:06

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:46
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:26:15

US3192006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:06

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:48
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:26:15

US3192006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:06

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:20:50
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:26:15

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.	(b) (4)	18 Feb 2021 20:40:36
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 16:06:22
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 03:57:52
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'reconciled' (Site from DM).	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:48
DataPoint Un-verified.	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:37
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 08:18:00
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:21:17
User entered '69.5' in	Tianna Young (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:06

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.	(b) (4)	30 Mar 2021 21:48:41
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:33:20
User closed query 'Per CDM: Kindly clear the units "kg" as weight was not recorded. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:23:39
Query 'Per CDM: Kindly clear the units "kg" as weight was not recorded. Thank you.' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	18 Mar 2021 15:09:42
DataPoint Un-verified.	maggie Tono (b) (4) (b) (4)	18 Mar 2021 15:09:25
Signature has been broken.	maggie Tono (b) (4) (b) (4)	18 Mar 2021 15:09:25
User entered missing code ND - Not Done; reason for change Data Entry Error	maggie Tono (b) (4) (b) (4)	18 Mar 2021 15:09:25
User opened query 'Per CDM: Kindly clear the units "kg" as weight was not recorded. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:12:16
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:40:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	13 Feb 2021 19:18:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	04 Sep 2020 16:06:22
DataPoint Un-verified.	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:37
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:21:19
User entered '218.6' lb	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.	(b) (4)	18 Feb 2021 20:40:36
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 16:06:22
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 03:57:52
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'reconciled' (Site from DM).	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:48
DataPoint Un-verified.	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:37
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 08:18:00
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:21:17
User entered '69.5' in	Tianna Young (b) (4)	02 Aug 2020 01:20:52
	(b) (4)	

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:06

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.		30 Mar 2021 21:48:41
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:33:20
User closed query 'Per CDM: Kindly clear the units "kg" as weight was not recorded. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:23:39
Query 'Per CDM: Kindly clear the units "kg" as weight was not recorded. Thank you.' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	18 Mar 2021 15:09:42
DataPoint Un-verified.	maggie Tono (b) (4) (b) (4)	18 Mar 2021 15:09:25
Signature has been broken.	maggie Tono (b) (4) (b) (4)	18 Mar 2021 15:09:25
User entered missing code ND - Not Done; reason for change Data Entry Error	maggie Tono (b) (4) (b) (4)	18 Mar 2021 15:09:25
User opened query 'Per CDM: Kindly clear the units "kg" as weight was not recorded. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:12:16
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:40:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	13 Feb 2021 19:18:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	04 Sep 2020 16:06:22
DataPoint Un-verified.	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:37
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:21:19
User entered '218.6' lb	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User accepted default value 'Pre-Dose (PREDOSE)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:22:14
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:22:14
User entered '1 Aug 2020'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:22:14
User entered '13:08'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered '1 Aug 2020 13:08'	System	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:22:14
User entered '97' F	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:22:14
User entered 'Other (Other)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:22:14
User entered 'Temporal'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:22:14
User entered '82'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'bpm'	System	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:22:14
User entered '16'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'breaths/min'	System	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:22:14
User entered '120'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'mmHg'	System	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:22:14
User entered '69'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'mmHg'	System	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.	(b) (4)	18 Feb 2021 20:40:36
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 16:06:22
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 03:57:52
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'reconciled' (Site from DM).	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:48
DataPoint Un-verified.	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:37
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 08:18:00
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:21:17
User entered '69.5' in	Tianna Young (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:06

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.		30 Mar 2021 21:48:41
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:33:20
User closed query 'Per CDM: Kindly clear the units "kg" as weight was not recorded. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:23:39
Query 'Per CDM: Kindly clear the units "kg" as weight was not recorded. Thank you.' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	18 Mar 2021 15:09:42
DataPoint Un-verified.	maggie Tono (b) (4) (b) (4)	18 Mar 2021 15:09:25
Signature has been broken.	maggie Tono (b) (4) (b) (4)	18 Mar 2021 15:09:25
User entered missing code ND - Not Done; reason for change Data Entry Error	maggie Tono (b) (4) (b) (4)	18 Mar 2021 15:09:25
User opened query 'Per CDM: Kindly clear the units "kg" as weight was not recorded. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:12:16
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 20:40:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	13 Feb 2021 19:18:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	04 Sep 2020 16:06:22
DataPoint Un-verified.	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	01 Sep 2020 16:34:37
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:21:19
User entered '218.6' lb	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:20:52

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User accepted default value 'Post-Dose (POSTDOSE)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:23:02
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:23:04
User entered '1 Aug 2020'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:23:07
User entered '14:42'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered '1 Aug 2020 14:42'	System	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:23:10
User entered '97.3' F	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:23:19
User entered 'Other (Other)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:23:20
User entered 'Temporal'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:23:25
User entered '77'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'bpm'	System	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:23:27
User entered '18'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'breaths/min'	System	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:23:30
User entered '112'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'mmHg'	System	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:23:32
User entered '60'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'mmHg'	System	02 Aug 2020 01:21:59

US3192006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:06

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.		18 Feb 2021 20:40:41
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Un-verified.	(b) (4)	
	Cynthia Montgomery	01 Sep 2020 17:53:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Sep 2020 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:23:42
User entered 'Yes (Y)'	Tianna Young (b) (4)	02 Aug 2020 01:22:18
	(b) (4)	

US3192006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.		18 Feb 2021 20:40:41
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Un-verified.	(b) (4)	
	Cynthia Montgomery	01 Sep 2020 17:53:04
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cynthia Montgomery	01 Sep 2020 17:53:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Aug 2020 18:23:42
User entered '1 Aug 2020'	Tianna Young (b) (4)	02 Aug 2020 01:22:18
	(b) (4)	

US3192006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:24:13
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:18:40

US3192006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:24:13
User entered empty.	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:18:40

US3192006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

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)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:24:13
User entered empty.	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:18:40

US3192006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'MRNA-1273 OR PLACEBO'	System	01 Aug 2020 21:18:40

US3192006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:24:13
User entered '1 Aug 2020'	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:18:40

US3192006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:24:13
User entered '13:39'	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:18:40

US3192006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered '1 Aug 2020 13:39'	System	01 Aug 2020 21:18:40

US3192006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:24:13
User entered 'Right Arm (RIGHT ARM)'	Tianna Young (b) (4) (b) (4)	01 Aug 2020 21:18:40

US3192006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.		07 Aug 2020 18:24:13
User entered 'ONCE'	System	01 Aug 2020 21:18:40

US3192006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'INTRAMUSCULAR'	System	01 Aug 2020 21:18:40

US3192006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:25:07
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:23:20

US3192006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:25:07
User entered '1 Aug 2020'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:23:20

US3192006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:25:07
User entered '13:25'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:23:20

US3192006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered '1 Aug 2020 13:25'	System	02 Aug 2020 01:23:20

US3192006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:39:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.		18 Feb 2021 20:40:53
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
User entered '1 Aug 2020'	(b) (4) Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:23:59

US3192006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:23:59

US3192006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:28:38
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:23:59

US3192006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:28:38
User entered '13:23'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:23:59

US3192006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered '1 Aug 2020 13:23'	System	02 Aug 2020 01:23:59

US3192006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:24:06

US3192006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.		30 Mar 2021 21:49:36
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
User entered 'No (N)'	(b) (4) Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:24:06

US3192006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.		30 Mar 2021 21:49:36
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
User entered empty.	(b) (4) Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:24:06

US3192006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered empty.	System	02 Aug 2020 01:24:06

US3192006

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 18:28:43
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:24:16

US3192006

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'I'	System	02 Aug 2020 01:24:16

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:25:25', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'b605b305-18ca-4ffe-b897-f62ccbe2d4fd' User entered 'Yes (Y)'	System	01 Aug 2020 21:26:52
	System	01 Aug 2020 21:26:52

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:26:32', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'b605b305-18ca-4ffe-b897-f62ccbe2d4fd' User entered '97.0'	System	01 Aug 2020 21:26:52
	System	01 Aug 2020 21:26:52

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:26:40', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'b605b305-18ca-4ffe-b897-f62ccbe2d4fd'	System	01 Aug 2020 21:26:52
User entered 'No (N)'	System	01 Aug 2020 21:26:52

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:26:50', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'b605b305-18ca-4ffe-b897-f62ccbe2d4fd'	System	01 Aug 2020 21:26:52
User entered '01 Aug 2020 14:26'	System	01 Aug 2020 21:26:52

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Aug 2020 13:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Aug 2020 16:29'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:49:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'e90f0b4e-7a4b-44b8-aa02-fb8487a35720'	System	02 Aug 2020 00:51:54
User entered 'Yes (Y)'	System	02 Aug 2020 00:51:54

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:51:39', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'e90f0b4e-7a4b-44b8-aa02-fb8487a35720' User entered '95.8'	System	02 Aug 2020 00:51:54
	System	02 Aug 2020 00:51:54

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:51:46', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'e90f0b4e-7a4b-44b8-aa02-fb8487a35720'	System	02 Aug 2020 00:51:54
User entered 'No (N)'	System	02 Aug 2020 00:51:54

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:51:52', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'e90f0b4e-7a4b-44b8-aa02-fb8487a35720'	System	02 Aug 2020 00:51:54
User entered '01 Aug 2020 17:51'	System	02 Aug 2020 00:51:54

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Aug 2020 17:24'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 2'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:01:01', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3a2e3fb6-5175-4b22-abc9-2d21c158a229' User entered 'Yes (Y)'	System	02 Aug 2020 19:01:29
	System	02 Aug 2020 19:01:29

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:01:16', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3a2e3fb6-5175-4b22-abc9-2d21c158a229' User entered '96.9'	System	02 Aug 2020 19:01:29
	System	02 Aug 2020 19:01:29

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:01:23', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3a2e3fb6-5175-4b22-abc9-2d21c158a229'	System	02 Aug 2020 19:01:29
User entered 'No (N)'	System	02 Aug 2020 19:01:29

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:01:27', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3a2e3fb6-5175-4b22-abc9-2d21c158a229' User entered '02 Aug 2020 12:01'	System	02 Aug 2020 19:01:29
	System	02 Aug 2020 19:01:29

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 3'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:17:03', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '2a8618da-bcf8-4a0f-bb1e-815840d1fae6' User entered 'Yes (Y)'	System	03 Aug 2020 21:17:23
	System	03 Aug 2020 21:17:23

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:17:10', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '2a8618da-bcf8-4a0f-bb1e-815840d1fae6' User entered '97.7'	System	03 Aug 2020 21:17:23
	System	03 Aug 2020 21:17:23

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:17:17', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '2a8618da-bcf8-4a0f-bb1e-815840d1fae6'	System	03 Aug 2020 21:17:23
User entered 'No (N)'	System	03 Aug 2020 21:17:23

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:17:21', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '2a8618da-bcf8-4a0f-bb1e-815840d1fae6'	System	03 Aug 2020 21:17:23
User entered '03 Aug 2020 14:17'	System	03 Aug 2020 21:17:23

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 4'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:29:23', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'bdcbee80-e4c3-44c7-a0b0-d4e3e0f67ee1' User entered 'Yes (Y)'	System	04 Aug 2020 22:29:45
	System	04 Aug 2020 22:29:45

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:29:29', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'bdcbee80-e4c3-44c7-a0b0-d4e3e0f67ee1' User entered '97.7'	System	04 Aug 2020 22:29:45
	System	04 Aug 2020 22:29:45

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:29:35', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'bdcbee80-e4c3-44c7-a0b0-d4e3e0f67ee1'	System	04 Aug 2020 22:29:45
User entered 'No (N)'	System	04 Aug 2020 22:29:45

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:29:40', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'bdcbee80-e4c3-44c7-a0b0-d4e3e0f67ee1' User entered '04 Aug 2020 15:29'	System	04 Aug 2020 22:29:45
	System	04 Aug 2020 22:29:45

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 5'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:33:43', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4fd56dd8-52fe-4c18-a7f1-f2a5726cd833'	System	05 Aug 2020 19:34:08
User entered 'Yes (Y)'	System	05 Aug 2020 19:34:08

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:33:55', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4fd56dd8-52fe-4c18-a7f1-f2a5726cd833'	System	05 Aug 2020 19:34:08
User entered '97.8'	System	05 Aug 2020 19:34:08

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:01', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4fd56dd8-52fe-4c18-a7f1-f2a5726cd833'	System	05 Aug 2020 19:34:08
User entered 'No (N)'	System	05 Aug 2020 19:34:08

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:05', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4fd56dd8-52fe-4c18-a7f1-f2a5726cd833'	System	05 Aug 2020 19:34:08
User entered '05 Aug 2020 12:34'	System	05 Aug 2020 19:34:08

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 6'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:58:46', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '020914ec-5b5c-437e-897d-e0c5851b1667' User entered 'Yes (Y)'	System	06 Aug 2020 20:59:07
	System	06 Aug 2020 20:59:07

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:58:53', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '020914ec-5b5c-437e-897d-e0c5851b1667' User entered '97.3'	System	06 Aug 2020 20:59:07
	System	06 Aug 2020 20:59:07

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:01', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '020914ec-5b5c-437e-897d-e0c5851b1667'	System	06 Aug 2020 20:59:07
User entered 'No (N)'	System	06 Aug 2020 20:59:07

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:05', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '020914ec-5b5c-437e-897d-e0c5851b1667'	System	06 Aug 2020 20:59:07
User entered '06 Aug 2020 13:59'	System	06 Aug 2020 20:59:07

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 7'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:44:47', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'c2efa0bc-9369-4c00-bae2-4604779b92f0' User entered 'Yes (Y)'	System	07 Aug 2020 22:45:06
	System	07 Aug 2020 22:45:06

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:44:53', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'c2efa0bc-9369-4c00-bae2-4604779b92f0' User entered '96.8'	System	07 Aug 2020 22:45:06
	System	07 Aug 2020 22:45:06

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:44:59', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'c2efa0bc-9369-4c00-bae2-4604779b92f0'	System	07 Aug 2020 22:45:06
User entered 'No (N)'	System	07 Aug 2020 22:45:06

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:04', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'c2efa0bc-9369-4c00-bae2-4604779b92f0' User entered '07 Aug 2020 15:45'	System	07 Aug 2020 22:45:06
	System	07 Aug 2020 22:45:06

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:27:27', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '7789d165-1fa0-4277-89ea-d0c894a81b99'	System	01 Aug 2020 21:27:44
User entered 'None (1)'	System	01 Aug 2020 21:27:44

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:27:30', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '7789d165-1fa0-4277-89ea-d0c894a81b99'	System	01 Aug 2020 21:27:44
User entered 'No (N)'	System	01 Aug 2020 21:27:44

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:27:33', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '7789d165-1fa0-4277-89ea-d0c894a81b99'	System	01 Aug 2020 21:27:44
User entered 'No (N)'	System	01 Aug 2020 21:27:44

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:27:37', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '7789d165-1fa0-4277-89ea-d0c894a81b99'	System	01 Aug 2020 21:27:44
User entered 'None (1)'	System	01 Aug 2020 21:27:44

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:27:41', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '7789d165-1fa0-4277-89ea-d0c894a81b99'	System	01 Aug 2020 21:27:44
User entered '01 Aug 2020 14:27'	System	01 Aug 2020 21:27:44

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Aug 2020 13:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Aug 2020 16:29'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:52:08', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '82f6ad3d-8e1e-46e9-8ad2-62aa89d223fe' User entered 'None (1)'	System	02 Aug 2020 00:52:35
	System	02 Aug 2020 00:52:35

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:52:13', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '82f6ad3d-8e1e-46e9-8ad2-62aa89d223fe' User entered 'No (N)'	System	02 Aug 2020 00:52:35
	System	02 Aug 2020 00:52:35

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:52:20', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '82f6ad3d-8e1e-46e9-8ad2-62aa89d223fe' User entered 'No (N)'	System	02 Aug 2020 00:52:35
	System	02 Aug 2020 00:52:35

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:52:28', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '82f6ad3d-8e1e-46e9-8ad2-62aa89d223fe' User entered 'None (1)'	System	02 Aug 2020 00:52:35
	System	02 Aug 2020 00:52:35

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:52:32', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '82f6ad3d-8e1e-46e9-8ad2-62aa89d223fe'	System	02 Aug 2020 00:52:35
User entered '01 Aug 2020 17:52'	System	02 Aug 2020 00:52:35

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Aug 2020 17:24'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 2'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:01:36', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9fe4add9-1fb3-45a2-b7db-b91b168252c4'	System	02 Aug 2020 19:02:00
User entered 'None (1)'	System	02 Aug 2020 19:02:00

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:01:41', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9fe4add9-1fb3-45a2-b7db-b91b168252c4' User entered 'No (N)'	System	02 Aug 2020 19:02:00
	System	02 Aug 2020 19:02:00

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:01:45', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9fe4add9-1fb3-45a2-b7db-b91b168252c4' User entered 'No (N)'	System	02 Aug 2020 19:02:00
	System	02 Aug 2020 19:02:00

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:01:55', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9fe4add9-1fb3-45a2-b7db-b91b168252c4' User entered 'None (1)'	System	02 Aug 2020 19:02:00
	System	02 Aug 2020 19:02:00

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:01:58', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9fe4add9-1fb3-45a2-b7db-b91b168252c4' User entered '02 Aug 2020 12:01'	System	02 Aug 2020 19:02:00
	System	02 Aug 2020 19:02:00

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 3'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:17:28', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'a073bed3-1469-4bb9-97c3-b10272a5dff5'	System	03 Aug 2020 21:17:52
User entered 'None (1)'	System	03 Aug 2020 21:17:52

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:17:33', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'a073bed3-1469-4bb9-97c3-b10272a5dff5'	System	03 Aug 2020 21:17:52
User entered 'No (N)'	System	03 Aug 2020 21:17:52

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:17:37', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'a073bed3-1469-4bb9-97c3-b10272a5dff5'	System	03 Aug 2020 21:17:52
User entered 'No (N)'	System	03 Aug 2020 21:17:52

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:17:43', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'a073bed3-1469-4bb9-97c3-b10272a5dff5'	System	03 Aug 2020 21:17:52
User entered 'None (1)'	System	03 Aug 2020 21:17:52

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:17:48', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'a073bed3-1469-4bb9-97c3-b10272a5dff5'	System	03 Aug 2020 21:17:52
User entered '03 Aug 2020 14:17'	System	03 Aug 2020 21:17:52

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 4'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:29:48', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '5bde4bbd-5309-42ed-9033-dd6f1026f211' User entered 'None (1)'	System	04 Aug 2020 22:30:06
	System	04 Aug 2020 22:30:06

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:29:53', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '5bde4bbd-5309-42ed-9033-dd6f1026f211' User entered 'No (N)'	System	04 Aug 2020 22:30:06
	System	04 Aug 2020 22:30:06

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:29:56', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '5bde4bbd-5309-42ed-9033-dd6f1026f211' User entered 'No (N)'	System	04 Aug 2020 22:30:06
	System	04 Aug 2020 22:30:06

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:30:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '5bde4bbd-5309-42ed-9033-dd6f1026f211' User entered 'None (1)'	System	04 Aug 2020 22:30:06
	System	04 Aug 2020 22:30:06

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:30:02', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '5bde4bbd-5309-42ed-9033-dd6f1026f211' User entered '04 Aug 2020 15:30'	System	04 Aug 2020 22:30:06
	System	04 Aug 2020 22:30:06

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 5'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:10', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3743f7e1-0b2a-42c5-812f-3e907880ae7c' User entered 'None (1)'	System	05 Aug 2020 19:34:26
	System	05 Aug 2020 19:34:26

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:13', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3743f7e1-0b2a-42c5-812f-3e907880ae7c' User entered 'No (N)'	System	05 Aug 2020 19:34:26
	System	05 Aug 2020 19:34:26

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:16', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3743f7e1-0b2a-42c5-812f-3e907880ae7c' User entered 'No (N)'	System	05 Aug 2020 19:34:26
	System	05 Aug 2020 19:34:26

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:19', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3743f7e1-0b2a-42c5-812f-3e907880ae7c' User entered 'None (1)'	System	05 Aug 2020 19:34:26
	System	05 Aug 2020 19:34:26

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:23', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3743f7e1-0b2a-42c5-812f-3e907880ae7c' User entered '05 Aug 2020 12:34'	System	05 Aug 2020 19:34:26
	System	05 Aug 2020 19:34:26

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 6'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:12', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cb5ec062-ba15-49d0-8840-caa1c4571876'	System	06 Aug 2020 20:59:27
User entered 'None (1)'	System	06 Aug 2020 20:59:27

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:15', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cb5ec062-ba15-49d0-8840-caa1c4571876' User entered 'No (N)'	System	06 Aug 2020 20:59:27
	System	06 Aug 2020 20:59:27

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:20', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cb5ec062-ba15-49d0-8840-caa1c4571876'	System	06 Aug 2020 20:59:27
User entered 'No (N)'	System	06 Aug 2020 20:59:27

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:23', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cb5ec062-ba15-49d0-8840-caa1c4571876' User entered 'None (1)'	System	06 Aug 2020 20:59:27
	System	06 Aug 2020 20:59:27

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:26', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cb5ec062-ba15-49d0-8840-caa1c4571876' User entered '06 Aug 2020 13:59'	System	06 Aug 2020 20:59:27
	System	06 Aug 2020 20:59:27

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 7'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:08', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9d7b8ed1-c2f6-4872-a203-0156ac9949cc' User entered 'None (1)'	System	07 Aug 2020 22:45:27
	System	07 Aug 2020 22:45:27

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:12', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9d7b8ed1-c2f6-4872-a203-0156ac9949cc' User entered 'No (N)'	System	07 Aug 2020 22:45:27
	System	07 Aug 2020 22:45:27

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:18', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9d7b8ed1-c2f6-4872-a203-0156ac9949cc' User entered 'No (N)'	System	07 Aug 2020 22:45:27
	System	07 Aug 2020 22:45:27

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:22', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9d7b8ed1-c2f6-4872-a203-0156ac9949cc' User entered 'None (1)'	System	07 Aug 2020 22:45:27
	System	07 Aug 2020 22:45:27

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:25', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9d7b8ed1-c2f6-4872-a203-0156ac9949cc' User entered '07 Aug 2020 15:45'	System	07 Aug 2020 22:45:27
	System	07 Aug 2020 22:45:27

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:27:52', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6e1a60f7-932c-4191-8f89-2f3361d2a572' User entered 'None (0)'	System	01 Aug 2020 21:28:37
	System	01 Aug 2020 21:28:37

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:28:01', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6e1a60f7-932c-4191-8f89-2f3361d2a572' User entered 'None (0)'	System	01 Aug 2020 21:28:37
	System	01 Aug 2020 21:28:37

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:28:09', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6e1a60f7-932c-4191-8f89-2f3361d2a572' User entered 'None (0)'	System	01 Aug 2020 21:28:37
	System	01 Aug 2020 21:28:37

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:28:14', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6e1a60f7-932c-4191-8f89-2f3361d2a572' User entered 'None (0)'	System	01 Aug 2020 21:28:37
	System	01 Aug 2020 21:28:37

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:28:18', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6e1a60f7-932c-4191-8f89-2f3361d2a572' User entered 'None (0)'	System	01 Aug 2020 21:28:37
	System	01 Aug 2020 21:28:37

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:28:21', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6e1a60f7-932c-4191-8f89-2f3361d2a572' User entered 'None (0)'	System	01 Aug 2020 21:28:37
	System	01 Aug 2020 21:28:37

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:28:30', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6e1a60f7-932c-4191-8f89-2f3361d2a572'	System	01 Aug 2020 21:28:37
User entered 'No (N)'	System	01 Aug 2020 21:28:37

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T14:28:34', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6e1a60f7-932c-4191-8f89-2f3361d2a572'	System	01 Aug 2020 21:28:37
User entered '01 Aug 2020 14:28'	System	01 Aug 2020 21:28:37

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Aug 2020 13:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Aug 2020 16:29'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:52:48', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '772a8479-f455-44a9-ad6b-f2f15b4fab01' User entered 'None (0)'	System	02 Aug 2020 00:53:23
	System	02 Aug 2020 00:53:23

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:52:54', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '772a8479-f455-44a9-ad6b-f2f15b4fab01' User entered 'None (0)'	System	02 Aug 2020 00:53:23
	System	02 Aug 2020 00:53:23

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:52:59', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '772a8479-f455-44a9-ad6b-f2f15b4fab01' User entered 'None (0)'	System	02 Aug 2020 00:53:23
	System	02 Aug 2020 00:53:23

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:53:02', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '772a8479-f455-44a9-ad6b-f2f15b4fab01' User entered 'None (0)'	System	02 Aug 2020 00:53:23
	System	02 Aug 2020 00:53:23

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:53:06', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '772a8479-f455-44a9-ad6b-f2f15b4fab01' User entered 'None (0)'	System	02 Aug 2020 00:53:23
	System	02 Aug 2020 00:53:23

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:53:10', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '772a8479-f455-44a9-ad6b-f2f15b4fab01' User entered 'None (0)'	System	02 Aug 2020 00:53:23
	System	02 Aug 2020 00:53:23

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:53:18', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '772a8479-f455-44a9-ad6b-f2f15b4fab01'	System	02 Aug 2020 00:53:23
User entered 'No (N)'	System	02 Aug 2020 00:53:23

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-01T17:53:22', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '772a8479-f455-44a9-ad6b-f2f15b4fab01'	System	02 Aug 2020 00:53:23
User entered '01 Aug 2020 17:53'	System	02 Aug 2020 00:53:23

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Aug 2020 17:24'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 2'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:02:04', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ea9f0712-55be-444d-8265-203e5aec0adc' User entered 'None (0)'	System	02 Aug 2020 19:02:42
	System	02 Aug 2020 19:02:42

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:02:09', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ea9f0712-55be-444d-8265-203e5aec0adc' User entered 'None (0)'	System	02 Aug 2020 19:02:42
	System	02 Aug 2020 19:02:42

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:02:17', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ea9f0712-55be-444d-8265-203e5aec0adc' User entered 'None (0)'	System	02 Aug 2020 19:02:42
	System	02 Aug 2020 19:02:42

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:02:21', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ea9f0712-55be-444d-8265-203e5aec0adc' User entered 'None (0)'	System	02 Aug 2020 19:02:42
	System	02 Aug 2020 19:02:42

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:02:25', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ea9f0712-55be-444d-8265-203e5aec0adc' User entered 'None (0)'	System	02 Aug 2020 19:02:42
	System	02 Aug 2020 19:02:42

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:02:28', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ea9f0712-55be-444d-8265-203e5aec0adc' User entered 'None (0)'	System	02 Aug 2020 19:02:42
	System	02 Aug 2020 19:02:42

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:02:36', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ea9f0712-55be-444d-8265-203e5aec0adc' User entered 'No (N)'	System	02 Aug 2020 19:02:42
	System	02 Aug 2020 19:02:42

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-02T12:02:41', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ea9f0712-55be-444d-8265-203e5aec0adc' User entered '02 Aug 2020 12:02'	System	02 Aug 2020 19:02:42
	System	02 Aug 2020 19:02:42

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 3'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:17:55', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '508d7de4-19d2-40be-be55-5e67a0b1c6be' User entered 'None (0)'	System	03 Aug 2020 21:18:28
	System	03 Aug 2020 21:18:28

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:17:58', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '508d7de4-19d2-40be-be55-5e67a0b1c6be' User entered 'None (0)'	System	03 Aug 2020 21:18:28
	System	03 Aug 2020 21:18:28

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:18:02', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '508d7de4-19d2-40be-be55-5e67a0b1c6be' User entered 'None (0)'	System	03 Aug 2020 21:18:28
	System	03 Aug 2020 21:18:28

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:18:05', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '508d7de4-19d2-40be-be55-5e67a0b1c6be' User entered 'None (0)'	System	03 Aug 2020 21:18:28
	System	03 Aug 2020 21:18:28

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:18:09', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '508d7de4-19d2-40be-be55-5e67a0b1c6be' User entered 'None (0)'	System	03 Aug 2020 21:18:28
	System	03 Aug 2020 21:18:28

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:18:13', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '508d7de4-19d2-40be-be55-5e67a0b1c6be' User entered 'None (0)'	System	03 Aug 2020 21:18:28
	System	03 Aug 2020 21:18:28

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:18:20', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '508d7de4-19d2-40be-be55-5e67a0b1c6be' User entered 'No (N)'	System	03 Aug 2020 21:18:28
	System	03 Aug 2020 21:18:28

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-03T14:18:23', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '508d7de4-19d2-40be-be55-5e67a0b1c6be' User entered '03 Aug 2020 14:18'	System	03 Aug 2020 21:18:28
	System	03 Aug 2020 21:18:28

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 4'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:30:08', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'eb33b358-7d61-4cc6-a7c2-753acafd1bb9' User entered 'None (0)'	System	04 Aug 2020 22:30:41
	System	04 Aug 2020 22:30:41

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:30:15', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'eb33b358-7d61-4cc6-a7c2-753acafd1bb9' User entered 'None (0)'	System	04 Aug 2020 22:30:41
	System	04 Aug 2020 22:30:41

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:30:20', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'eb33b358-7d61-4cc6-a7c2-753acafd1bb9' User entered 'None (0)'	System	04 Aug 2020 22:30:41
	System	04 Aug 2020 22:30:41

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:30:23', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'eb33b358-7d61-4cc6-a7c2-753acafd1bb9' User entered 'None (0)'	System	04 Aug 2020 22:30:41
	System	04 Aug 2020 22:30:41

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:30:28', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'eb33b358-7d61-4cc6-a7c2-753acafd1bb9' User entered 'None (0)'	System	04 Aug 2020 22:30:41
	System	04 Aug 2020 22:30:41

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:30:32', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'eb33b358-7d61-4cc6-a7c2-753acafd1bb9' User entered 'None (0)'	System	04 Aug 2020 22:30:41
	System	04 Aug 2020 22:30:41

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:30:36', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'eb33b358-7d61-4cc6-a7c2-753acafd1bb9' User entered 'No (N)'	System	04 Aug 2020 22:30:41
	System	04 Aug 2020 22:30:41

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-04T15:30:39', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'eb33b358-7d61-4cc6-a7c2-753acafd1bb9'	System	04 Aug 2020 22:30:41
User entered '04 Aug 2020 15:30'	System	04 Aug 2020 22:30:41

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 5'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:31', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '24375eb0-c60d-4ab5-a615-388c24225a27' User entered 'None (0)'	System	05 Aug 2020 19:35:03
	System	05 Aug 2020 19:35:03

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:34', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '24375eb0-c60d-4ab5-a615-388c24225a27' User entered 'None (0)'	System	05 Aug 2020 19:35:03
	System	05 Aug 2020 19:35:03

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:37', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '24375eb0-c60d-4ab5-a615-388c24225a27' User entered 'None (0)'	System	05 Aug 2020 19:35:03
	System	05 Aug 2020 19:35:03

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:42', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '24375eb0-c60d-4ab5-a615-388c24225a27' User entered 'None (0)'	System	05 Aug 2020 19:35:03
	System	05 Aug 2020 19:35:03

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:45', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '24375eb0-c60d-4ab5-a615-388c24225a27' User entered 'None (0)'	System	05 Aug 2020 19:35:03
	System	05 Aug 2020 19:35:03

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:48', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '24375eb0-c60d-4ab5-a615-388c24225a27' User entered 'None (0)'	System	05 Aug 2020 19:35:03
	System	05 Aug 2020 19:35:03

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:56', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '24375eb0-c60d-4ab5-a615-388c24225a27' User entered 'No (N)'	System	05 Aug 2020 19:35:03
	System	05 Aug 2020 19:35:03

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-05T12:34:59', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '24375eb0-c60d-4ab5-a615-388c24225a27'	System	05 Aug 2020 19:35:03
User entered '05 Aug 2020 12:34'	System	05 Aug 2020 19:35:03

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 6'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:33', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cd8a68b7-f736-42bb-8c9b-7e81ffb5b496'	System	06 Aug 2020 21:00:04
User entered 'None (0)'	System	06 Aug 2020 21:00:04

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:37', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cd8a68b7-f736-42bb-8c9b-7e81ffb5b496'	System	06 Aug 2020 21:00:04
User entered 'None (0)'	System	06 Aug 2020 21:00:04

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:40', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cd8a68b7-f736-42bb-8c9b-7e81ffb5b496' User entered 'None (0)'	System	06 Aug 2020 21:00:04
	System	06 Aug 2020 21:00:04

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:43', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cd8a68b7-f736-42bb-8c9b-7e81ffb5b496' User entered 'None (0)'	System	06 Aug 2020 21:00:04
	System	06 Aug 2020 21:00:04

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:46', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cd8a68b7-f736-42bb-8c9b-7e81ffb5b496' User entered 'None (0)'	System	06 Aug 2020 21:00:04
	System	06 Aug 2020 21:00:04

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:49', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cd8a68b7-f736-42bb-8c9b-7e81ffb5b496' User entered 'None (0)'	System	06 Aug 2020 21:00:04
	System	06 Aug 2020 21:00:04

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:55', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cd8a68b7-f736-42bb-8c9b-7e81ffb5b496'	System	06 Aug 2020 21:00:04
User entered 'No (N)'	System	06 Aug 2020 21:00:04

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-06T13:59:57', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cd8a68b7-f736-42bb-8c9b-7e81ffb5b496'	System	06 Aug 2020 21:00:04
User entered '06 Aug 2020 13:59'	System	06 Aug 2020 21:00:04

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 7'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:29', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '35cba024-13b7-46f8-9f82-46d8c1299ab0' User entered 'None (0)'	System	07 Aug 2020 22:45:55
	System	07 Aug 2020 22:45:55

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:31', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '35cba024-13b7-46f8-9f82-46d8c1299ab0' User entered 'None (0)'	System	07 Aug 2020 22:45:55
	System	07 Aug 2020 22:45:55

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:34', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '35cba024-13b7-46f8-9f82-46d8c1299ab0' User entered 'None (0)'	System	07 Aug 2020 22:45:55
	System	07 Aug 2020 22:45:55

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:37', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '35cba024-13b7-46f8-9f82-46d8c1299ab0' User entered 'None (0)'	System	07 Aug 2020 22:45:55
	System	07 Aug 2020 22:45:55

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:40', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '35cba024-13b7-46f8-9f82-46d8c1299ab0' User entered 'None (0)'	System	07 Aug 2020 22:45:55
	System	07 Aug 2020 22:45:55

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:42', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '35cba024-13b7-46f8-9f82-46d8c1299ab0' User entered 'None (0)'	System	07 Aug 2020 22:45:55
	System	07 Aug 2020 22:45:55

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:48', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '35cba024-13b7-46f8-9f82-46d8c1299ab0' User entered 'No (N)'	System	07 Aug 2020 22:45:55
	System	07 Aug 2020 22:45:55

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-07T15:45:51', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '35cba024-13b7-46f8-9f82-46d8c1299ab0' User entered '07 Aug 2020 15:45'	System	07 Aug 2020 22:45:55
	System	07 Aug 2020 22:45:55

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 21:18:40

US3192006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:29:42
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	08 Aug 2020 23:13:03

US3192006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:29:42
User entered '8 Aug 2020'	Tianna Young (b) (4) (b) (4)	08 Aug 2020 23:13:03

US3192006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:29:42
User entered 'Contact Made (CONTACT MADE)'	Tianna Young (b) (4) (b) (4)	08 Aug 2020 23:13:03

US3192006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:29:42
User entered empty.	Tianna Young (b) (4) (b) (4)	08 Aug 2020 23:13:03

US3192006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:29:46
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	08 Aug 2020 23:13:08

US3192006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'I'	System	08 Aug 2020 23:13:08

US3192006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:30:13
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	16 Aug 2020 18:06:03

US3192006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:30:13
User entered '15 Aug 2020'	Saysamone Banks (b) (4) (b) (4)	16 Aug 2020 18:06:03

US3192006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:30:13
User entered 'Contact Made (CONTACT MADE)'	Saysamone Banks (b) (4) (b) (4)	16 Aug 2020 18:06:03

US3192006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:30:13
User entered empty.	Saysamone Banks (b) (4) (b) (4)	16 Aug 2020 18:06:03

US3192006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:30:18
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	16 Aug 2020 18:06:08

US3192006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'I'	System	16 Aug 2020 18:06:08

US3192006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:30:32
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	29 Aug 2020 02:46:16

US3192006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:30:32
User entered '22 Aug 2020'	Yvonne De Los Reyes (b) (4)	29 Aug 2020 02:46:16

US3192006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:30:32
User entered 'Contact Made (CONTACT MADE)'	Yvonne De Los Reyes (b) (4)	29 Aug 2020 02:46:16

US3192006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:30:32
User entered empty.	Yvonne De Los Reyes (b) (4)	29 Aug 2020 02:46:16

US3192006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:30:36
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	29 Aug 2020 02:46:04

US3192006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'I'	System	29 Aug 2020 02:46:04

US3192006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:04
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:02

US3192006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:04
User entered '29 Aug 2020'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:02

US3192006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:04
User entered 'Clinic (Clinic)'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:02

US3192006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'VISIT2'	System	29 Aug 2020 23:58:02

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User accepted default value 'Pre-Dose (PREDOSE)'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:30
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:31
User entered '29 Aug 2020'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:35
User entered '14:40'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered '29 Aug 2020 14:40'	System	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:38
User entered '97.7' F	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:43
User entered 'Oral (Oral)'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:45
User entered empty.	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:49
User entered '74'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'bpm'	System	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:51
User entered '16'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'breaths/min'	System	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:53
User entered '138'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'mmHg'	System	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:31:55
User entered '80'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'mmHg'	System	30 Aug 2020 00:00:06

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User accepted default value 'Post-Dose (POSTDOSE)'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:32:13
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:32:14
User entered '29 Aug 2020'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:32:17
User entered '16:00'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered '29 Aug 2020 16:00'	System	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:32:22
User entered '97.4' F	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:32:24
User entered 'Oral (Oral)'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:32:26
User entered empty.	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:32:28
User entered '70'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'bpm'	System	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:32:30
User entered '14'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'breaths/min'	System	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:32:32
User entered '134'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'mmHg'	System	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:32:34
User entered '67'	Tianna Young (b) (4) (b) (4)	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'mmHg'	System	30 Aug 2020 00:01:20

US3192006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:13
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:10

US3192006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:13
User entered '29 Aug 2020'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:10

US3192006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:39
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	29 Aug 2020 22:27:40

US3192006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:39
User entered empty.	Zoe Sesma (b) (4) (b) (4)	29 Aug 2020 22:27:40

US3192006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

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)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:39
User entered empty.	Zoe Sesma (b) (4) (b) (4)	29 Aug 2020 22:27:40

US3192006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 22:27:40

US3192006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:39
User entered '29 Aug 2020'	Zoe Sesma (b) (4) (b) (4)	29 Aug 2020 22:27:40

US3192006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:39
User entered '15:26'	Zoe Sesma (b) (4) (b) (4)	29 Aug 2020 22:27:40

US3192006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered '29 Aug 2020 15:26'	System	29 Aug 2020 22:27:40

US3192006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:39
User entered 'Right Arm (RIGHT ARM)'	Zoe Sesma (b) (4) (b) (4)	29 Aug 2020 22:27:40

US3192006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
DataPoint Verified.		02 Sep 2020 18:33:39
User entered 'ONCE'	System	29 Aug 2020 22:27:40

US3192006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 22:27:40

US3192006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:53
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:59:01

US3192006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:53
User entered '29 Aug 2020'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:59:01

US3192006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:53
User entered '15:12'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:59:01

US3192006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered '29 Aug 2020 15:12'	System	29 Aug 2020 23:59:01

US3192006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:39:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:34:01
User entered '29 Aug 2020'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:33

US3192006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:33

US3192006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:34:01
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:33

US3192006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:34:01
User entered '15:10'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:33

US3192006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered '29 Aug 2020 15:10'	System	29 Aug 2020 23:58:33

US3192006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:33

US3192006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:34:01
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:33

US3192006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:34:01
User entered empty.	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:33

US3192006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered empty.	System	29 Aug 2020 23:58:33

US3192006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:34:04
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	29 Aug 2020 23:58:39

US3192006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'I'	System	29 Aug 2020 23:58:39

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T15:58:38', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'e4a1e646-4db6-4b04-933a-92196ccef05'	System	29 Aug 2020 22:59:03
User entered 'Yes (Y)'	System	29 Aug 2020 22:59:03

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T15:58:46', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'e4a1e646-4db6-4b04-933a-92196ccef05' User entered '97.4'	System	29 Aug 2020 22:59:03
	System	29 Aug 2020 22:59:03

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T15:58:51', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'e4a1e646-4db6-4b04-933a-92196ccef05'	System	29 Aug 2020 22:59:03
User entered 'No (N)'	System	29 Aug 2020 22:59:03

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T15:58:59', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'e4a1e646-4db6-4b04-933a-92196ccef05'	System	29 Aug 2020 22:59:03
User entered '29 Aug 2020 15:58'	System	29 Aug 2020 22:59:03

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '29 Aug 2020 15:46'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '29 Aug 2020 18:16'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:15:58', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6585309f-ea41-4749-8c38-9a6b3b1430d4' User entered 'Yes (Y)'	System	30 Aug 2020 04:16:49
	System	30 Aug 2020 04:16:49

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:16:29', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6585309f-ea41-4749-8c38-9a6b3b1430d4' User entered '96.8'	System	30 Aug 2020 04:16:49
	System	30 Aug 2020 04:16:49

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:16:34', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6585309f-ea41-4749-8c38-9a6b3b1430d4' User entered 'No (N)'	System	30 Aug 2020 04:16:49
	System	30 Aug 2020 04:16:49

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:16:47', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6585309f-ea41-4749-8c38-9a6b3b1430d4' User entered '29 Aug 2020 21:16'	System	30 Aug 2020 04:16:49
	System	30 Aug 2020 04:16:49

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '29 Aug 2020 19:11'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 2'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 3'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:00:31', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f3545cd5-80d3-4fd3-8373-2e5147320287' User entered 'Yes (Y)'	System	31 Aug 2020 19:00:51
	System	31 Aug 2020 19:00:51

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:00:38', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f3545cd5-80d3-4fd3-8373-2e5147320287' User entered '97.7'	System	31 Aug 2020 19:00:51
	System	31 Aug 2020 19:00:51

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:00:46', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f3545cd5-80d3-4fd3-8373-2e5147320287'	System	31 Aug 2020 19:00:51
User entered 'No (N)'	System	31 Aug 2020 19:00:51

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:00:49', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f3545cd5-80d3-4fd3-8373-2e5147320287'	System	31 Aug 2020 19:00:51
User entered '31 Aug 2020 12:00'	System	31 Aug 2020 19:00:51

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 4'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:15:19', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '7ff310cd-f0eb-4b02-980b-55359c39259c' User entered 'Yes (Y)'	System	02 Sep 2020 02:16:15
	System	02 Sep 2020 02:16:15

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:15:25', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '7ff310cd-f0eb-4b02-980b-55359c39259c' User entered '97.1'	System	02 Sep 2020 02:16:15
	System	02 Sep 2020 02:16:15

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:15:31', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '7ff310cd-f0eb-4b02-980b-55359c39259c'	System	02 Sep 2020 02:16:15
User entered 'No (N)'	System	02 Sep 2020 02:16:15

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:15:36', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '7ff310cd-f0eb-4b02-980b-55359c39259c'	System	02 Sep 2020 02:16:15
User entered '01 Sep 2020 19:15'	System	02 Sep 2020 02:16:15

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 5'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:43:19', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3fd5bde4-e21a-427b-be74-4cdb1e776a50' User entered 'Yes (Y)'	System	03 Sep 2020 02:43:36
	System	03 Sep 2020 02:43:36

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:43:25', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3fd5bde4-e21a-427b-be74-4cdb1e776a50' User entered '97.0'	System	03 Sep 2020 02:43:36
	System	03 Sep 2020 02:43:36

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:43:30', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3fd5bde4-e21a-427b-be74-4cdb1e776a50'	System	03 Sep 2020 02:43:36
User entered 'No (N)'	System	03 Sep 2020 02:43:36

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:43:34', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3fd5bde4-e21a-427b-be74-4cdb1e776a50'	System	03 Sep 2020 02:43:36
User entered '02 Sep 2020 19:43'	System	03 Sep 2020 02:43:36

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 6'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:36:29', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'a2a2a15e-aecc-4c9f-80d5-86eb9aaa1c30' User entered 'Yes (Y)'	System	03 Sep 2020 19:36:50
	System	03 Sep 2020 19:36:50

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:36:37', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'a2a2a15e-aecc-4c9f-80d5-86eb9aaa1c30' User entered '97.7'	System	03 Sep 2020 19:36:50
	System	03 Sep 2020 19:36:50

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:36:41', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'a2a2a15e-aecc-4c9f-80d5-86eb9aaa1c30'	System	03 Sep 2020 19:36:50
User entered 'No (N)'	System	03 Sep 2020 19:36:50

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:36:45', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'a2a2a15e-aecc-4c9f-80d5-86eb9aaa1c30'	System	03 Sep 2020 19:36:50
User entered '03 Sep 2020 12:36'	System	03 Sep 2020 19:36:50

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 7'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T17:59:49', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ac9c5932-4812-4e2d-bd7f-308ee95a59'	System	05 Sep 2020 01:00:12
User entered 'Yes (Y)'	System	05 Sep 2020 01:00:12

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T17:59:56', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ac9c5932-4812-4e2d-bd7f-308ee95a59' User entered '98.3'	System	05 Sep 2020 01:00:12
	System	05 Sep 2020 01:00:12

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:05', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ac9c5932-4812-4e2d-bd7f-308ee95a59'	System	05 Sep 2020 01:00:12
User entered 'No (N)'	System	05 Sep 2020 01:00:12

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:09', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ac9c5932-4812-4e2d-bd7f-308ee95a59'	System	05 Sep 2020 01:00:12
User entered '04 Sep 2020 18:00'	System	05 Sep 2020 01:00:12

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T15:59:28', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '2ed19485-e8b1-4f5b-95e2-9315d5a2872d' User entered 'None (1)'	System	29 Aug 2020 22:59:47
	System	29 Aug 2020 22:59:47

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T15:59:32', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '2ed19485-e8b1-4f5b-95e2-9315d5a2872d' User entered 'No (N)'	System	29 Aug 2020 22:59:47
	System	29 Aug 2020 22:59:47

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T15:59:36', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '2ed19485-e8b1-4f5b-95e2-9315d5a2872d' User entered 'No (N)'	System	29 Aug 2020 22:59:47
	System	29 Aug 2020 22:59:47

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T15:59:40', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '2ed19485-e8b1-4f5b-95e2-9315d5a2872d' User entered 'None (1)'	System	29 Aug 2020 22:59:47
	System	29 Aug 2020 22:59:47

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T15:59:43', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '2ed19485-e8b1-4f5b-95e2-9315d5a2872d' User entered '29 Aug 2020 15:59'	System	29 Aug 2020 22:59:47
	System	29 Aug 2020 22:59:47

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '29 Aug 2020 15:46'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '29 Aug 2020 18:16'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:16:54', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '114d20b0-7af9-432c-b723-4b0acdacf3f4'	System	30 Aug 2020 04:17:29
User entered 'None (1)'	System	30 Aug 2020 04:17:29

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:17:14', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '114d20b0-7af9-432c-b723-4b0acdacf3f4'	System	30 Aug 2020 04:17:29
User entered 'No (N)'	System	30 Aug 2020 04:17:29

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:17:17', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '114d20b0-7af9-432c-b723-4b0acdacf3f4'	System	30 Aug 2020 04:17:29
User entered 'No (N)'	System	30 Aug 2020 04:17:29

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:17:21', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '114d20b0-7af9-432c-b723-4b0acdacf3f4'	System	30 Aug 2020 04:17:29
User entered 'None (1)'	System	30 Aug 2020 04:17:29

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:17:25', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '114d20b0-7af9-432c-b723-4b0acdacf3f4'	System	30 Aug 2020 04:17:29
User entered '29 Aug 2020 21:17'	System	30 Aug 2020 04:17:29

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '29 Aug 2020 19:11'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 2'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 3'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:00:54', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6027a078-e586-48bc-9c13-d69969400bff' User entered 'None (1)'	System	31 Aug 2020 19:01:39
	System	31 Aug 2020 19:01:39

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:00:59', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6027a078-e586-48bc-9c13-d69969400bff' User entered 'No (N)'	System	31 Aug 2020 19:01:39
	System	31 Aug 2020 19:01:39

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:01:02', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6027a078-e586-48bc-9c13-d69969400bff' User entered 'No (N)'	System	31 Aug 2020 19:01:39
	System	31 Aug 2020 19:01:39

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:01:04', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6027a078-e586-48bc-9c13-d69969400bff' User entered 'None (1)'	System	31 Aug 2020 19:01:39
	System	31 Aug 2020 19:01:39

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:01:07', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6027a078-e586-48bc-9c13-d69969400bff' User entered '31 Aug 2020 12:01'	System	31 Aug 2020 19:01:39
	System	31 Aug 2020 19:01:39

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 4'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:15:41', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f033bb0b-1b2e-4a54-be55-e07b862a125a' User entered 'None (1)'	System	02 Sep 2020 02:16:32
	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:15:45', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f033bb0b-1b2e-4a54-be55-e07b862a125a' User entered 'No (N)'	System	02 Sep 2020 02:16:32
	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:15:48', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f033bb0b-1b2e-4a54-be55-e07b862a125a' User entered 'No (N)'	System	02 Sep 2020 02:16:32
	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:15:53', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f033bb0b-1b2e-4a54-be55-e07b862a125a' User entered 'None (1)'	System	02 Sep 2020 02:16:32
	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:15:56', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f033bb0b-1b2e-4a54-be55-e07b862a125a' User entered '01 Sep 2020 19:15'	System	02 Sep 2020 02:16:32
	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 5'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:43:39', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '31244984-7afc-454e-8eec-5d77860f7efa' User entered 'None (1)'	System	03 Sep 2020 02:43:55
	System	03 Sep 2020 02:43:55

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:43:43', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '31244984-7afc-454e-8eec-5d77860f7efa' User entered 'No (N)'	System	03 Sep 2020 02:43:55
	System	03 Sep 2020 02:43:55

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:43:46', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '31244984-7afc-454e-8eec-5d77860f7efa' User entered 'No (N)'	System	03 Sep 2020 02:43:55
	System	03 Sep 2020 02:43:55

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:43:50', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '31244984-7afc-454e-8eec-5d77860f7efa' User entered 'None (1)'	System	03 Sep 2020 02:43:55
	System	03 Sep 2020 02:43:55

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:43:52', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '31244984-7afc-454e-8eec-5d77860f7efa' User entered '02 Sep 2020 19:43'	System	03 Sep 2020 02:43:55
	System	03 Sep 2020 02:43:55

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 6'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:36:50', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6fd2ef90-f937-45b9-b5dc-8556f5703e49'	System	03 Sep 2020 19:37:04
User entered 'None (1)'	System	03 Sep 2020 19:37:04

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:36:54', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6fd2ef90-f937-45b9-b5dc-8556f5703e49'	System	03 Sep 2020 19:37:04
User entered 'No (N)'	System	03 Sep 2020 19:37:04

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:36:57', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6fd2ef90-f937-45b9-b5dc-8556f5703e49'	System	03 Sep 2020 19:37:04
User entered 'No (N)'	System	03 Sep 2020 19:37:04

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:36:59', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6fd2ef90-f937-45b9-b5dc-8556f5703e49'	System	03 Sep 2020 19:37:04
User entered 'None (1)'	System	03 Sep 2020 19:37:04

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:37:02', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '6fd2ef90-f937-45b9-b5dc-8556f5703e49' User entered '03 Sep 2020 12:37'	System	03 Sep 2020 19:37:04
	System	03 Sep 2020 19:37:04

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 7'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:14', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'dbe6e2c9-8a03-4c14-9686-9d98d36d254d' User entered 'None (1)'	System	05 Sep 2020 01:00:35
	System	05 Sep 2020 01:00:35

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:19', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'dbe6e2c9-8a03-4c14-9686-9d98d36d254d' User entered 'No (N)'	System	05 Sep 2020 01:00:35
	System	05 Sep 2020 01:00:35

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:24', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'dbe6e2c9-8a03-4c14-9686-9d98d36d254d' User entered 'No (N)'	System	05 Sep 2020 01:00:35
	System	05 Sep 2020 01:00:35

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:28', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'dbef6e2c9-8a03-4c14-9686-9d98d36d254d'	System	05 Sep 2020 01:00:35
User entered 'None (1)'	System	05 Sep 2020 01:00:35

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:31', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'dbe6e2c9-8a03-4c14-9686-9d98d36d254d' User entered '04 Sep 2020 18:00'	System	05 Sep 2020 01:00:35
	System	05 Sep 2020 01:00:35

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T15:59:53', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3e0b311e-5f74-4ed8-9423-87f570095ca1' User entered 'None (0)'	System	29 Aug 2020 23:00:20
	System	29 Aug 2020 23:00:20

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T15:59:56', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3e0b311e-5f74-4ed8-9423-87f570095ca1' User entered 'None (0)'	System	29 Aug 2020 23:00:20
	System	29 Aug 2020 23:00:20

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T15:59:59', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3e0b311e-5f74-4ed8-9423-87f570095ca1' User entered 'None (0)'	System	29 Aug 2020 23:00:20
	System	29 Aug 2020 23:00:20

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T16:00:03', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3e0b311e-5f74-4ed8-9423-87f570095ca1' User entered 'None (0)'	System	29 Aug 2020 23:00:20
	System	29 Aug 2020 23:00:20

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T16:00:05', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3e0b311e-5f74-4ed8-9423-87f570095ca1' User entered 'None (0)'	System	29 Aug 2020 23:00:20
	System	29 Aug 2020 23:00:20

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T16:00:09', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3e0b311e-5f74-4ed8-9423-87f570095ca1' User entered 'None (0)'	System	29 Aug 2020 23:00:20
	System	29 Aug 2020 23:00:20

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T16:00:14', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3e0b311e-5f74-4ed8-9423-87f570095ca1' User entered 'No (N)'	System	29 Aug 2020 23:00:20
	System	29 Aug 2020 23:00:20

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T16:00:16', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '3e0b311e-5f74-4ed8-9423-87f570095ca1' User entered '29 Aug 2020 16:00'	System	29 Aug 2020 23:00:20
	System	29 Aug 2020 23:00:20

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '29 Aug 2020 15:46'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '29 Aug 2020 18:16'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:17:30', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e8053ee-4ed5-4a18-b9d8-76c503643bad' User entered 'None (0)'	System	30 Aug 2020 04:17:56
	System	30 Aug 2020 04:17:56

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:17:35', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e8053ee-4ed5-4a18-b9d8-76c503643bad' User entered 'None (0)'	System	30 Aug 2020 04:17:56
	System	30 Aug 2020 04:17:56

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:17:37', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e8053ee-4ed5-4a18-b9d8-76c503643bad' User entered 'None (0)'	System	30 Aug 2020 04:17:56
	System	30 Aug 2020 04:17:56

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:17:40', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e8053ee-4ed5-4a18-b9d8-76c503643bad' User entered 'None (0)'	System	30 Aug 2020 04:17:56
	System	30 Aug 2020 04:17:56

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:17:43', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e8053ee-4ed5-4a18-b9d8-76c503643bad' User entered 'None (0)'	System	30 Aug 2020 04:17:56
	System	30 Aug 2020 04:17:56

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:17:46', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e8053ee-4ed5-4a18-b9d8-76c503643bad' User entered 'None (0)'	System	30 Aug 2020 04:17:56
	System	30 Aug 2020 04:17:56

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:17:51', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e8053ee-4ed5-4a18-b9d8-76c503643bad' User entered 'No (N)'	System	30 Aug 2020 04:17:56
	System	30 Aug 2020 04:17:56

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-29T21:17:54', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e8053ee-4ed5-4a18-b9d8-76c503643bad' User entered '29 Aug 2020 21:17'	System	30 Aug 2020 04:17:56
	System	30 Aug 2020 04:17:56

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '29 Aug 2020 19:11'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 2'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 3'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:01:12', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f5bb764a-5307-4761-8eab-6349ba54c156' User entered 'None (0)'	System	31 Aug 2020 19:02:09
	System	31 Aug 2020 19:02:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:01:15', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f5bb764a-5307-4761-8eab-6349ba54c156' User entered 'None (0)'	System	31 Aug 2020 19:02:09
	System	31 Aug 2020 19:02:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:01:19', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f5bb764a-5307-4761-8eab-6349ba54c156' User entered 'None (0)'	System	31 Aug 2020 19:02:09
	System	31 Aug 2020 19:02:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:01:21', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f5bb764a-5307-4761-8eab-6349ba54c156' User entered 'None (0)'	System	31 Aug 2020 19:02:09
	System	31 Aug 2020 19:02:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:01:24', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f5bb764a-5307-4761-8eab-6349ba54c156' User entered 'None (0)'	System	31 Aug 2020 19:02:09
	System	31 Aug 2020 19:02:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:01:27', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f5bb764a-5307-4761-8eab-6349ba54c156' User entered 'None (0)'	System	31 Aug 2020 19:02:09
	System	31 Aug 2020 19:02:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:01:37', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f5bb764a-5307-4761-8eab-6349ba54c156' User entered 'No (N)'	System	31 Aug 2020 19:02:09
	System	31 Aug 2020 19:02:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-08-31T12:01:40', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f5bb764a-5307-4761-8eab-6349ba54c156' User entered '31 Aug 2020 12:01'	System	31 Aug 2020 19:02:09
	System	31 Aug 2020 19:02:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 4'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:16:03', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e3c8105-8dbd-492e-ae59-ec9f94e3cd59' User entered 'None (0)'	System	02 Sep 2020 02:16:32
	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:16:07', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e3c8105-8dbd-492e-ae59-ec9f94e3cd59' User entered 'None (0)'	System	02 Sep 2020 02:16:32
	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:16:09', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e3c8105-8dbd-492e-ae59-ec9f94e3cd59' User entered 'None (0)'	System	02 Sep 2020 02:16:32
	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:16:15', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e3c8105-8dbd-492e-ae59-ec9f94e3cd59' User entered 'None (0)'	System	02 Sep 2020 02:16:32
	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:16:18', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e3c8105-8dbd-492e-ae59-ec9f94e3cd59' User entered 'None (0)'	System	02 Sep 2020 02:16:32
	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:16:20', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e3c8105-8dbd-492e-ae59-ec9f94e3cd59' User entered 'None (0)'	System	02 Sep 2020 02:16:32
	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:16:25', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e3c8105-8dbd-492e-ae59-ec9f94e3cd59' User entered 'No (N)'	System	02 Sep 2020 02:16:32
	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-01T19:16:28', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4e3c8105-8dbd-492e-ae59-ec9f94e3cd59'	System	02 Sep 2020 02:16:32
User entered '01 Sep 2020 19:16'	System	02 Sep 2020 02:16:32

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 5'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:43:58', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9731d035-431f-46aa-8e7f-b084e6d8c3fe' User entered 'None (0)'	System	03 Sep 2020 02:44:21
	System	03 Sep 2020 02:44:21

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:44:01', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9731d035-431f-46aa-8e7f-b084e6d8c3fe' User entered 'None (0)'	System	03 Sep 2020 02:44:21
	System	03 Sep 2020 02:44:21

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:44:04', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9731d035-431f-46aa-8e7f-b084e6d8c3fe' User entered 'None (0)'	System	03 Sep 2020 02:44:21
	System	03 Sep 2020 02:44:21

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:44:08', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9731d035-431f-46aa-8e7f-b084e6d8c3fe' User entered 'None (0)'	System	03 Sep 2020 02:44:21
	System	03 Sep 2020 02:44:21

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:44:10', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9731d035-431f-46aa-8e7f-b084e6d8c3fe' User entered 'None (0)'	System	03 Sep 2020 02:44:21
	System	03 Sep 2020 02:44:21

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:44:13', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9731d035-431f-46aa-8e7f-b084e6d8c3fe' User entered 'None (0)'	System	03 Sep 2020 02:44:21
	System	03 Sep 2020 02:44:21

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:44:16', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9731d035-431f-46aa-8e7f-b084e6d8c3fe' User entered 'No (N)'	System	03 Sep 2020 02:44:21
	System	03 Sep 2020 02:44:21

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-02T19:44:19', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9731d035-431f-46aa-8e7f-b084e6d8c3fe' User entered '02 Sep 2020 19:44'	System	03 Sep 2020 02:44:21
	System	03 Sep 2020 02:44:21

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 6'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:37:06', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cc9649bd-ab35-44d7-9a67-649e66b810d8' User entered 'None (0)'	System	03 Sep 2020 19:37:35
	System	03 Sep 2020 19:37:35

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:37:10', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cc9649bd-ab35-44d7-9a67-649e66b810d8' User entered 'None (0)'	System	03 Sep 2020 19:37:35
	System	03 Sep 2020 19:37:35

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:37:13', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cc9649bd-ab35-44d7-9a67-649e66b810d8' User entered 'None (0)'	System	03 Sep 2020 19:37:35
	System	03 Sep 2020 19:37:35

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:37:17', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cc9649bd-ab35-44d7-9a67-649e66b810d8' User entered 'None (0)'	System	03 Sep 2020 19:37:35
	System	03 Sep 2020 19:37:35

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:37:20', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cc9649bd-ab35-44d7-9a67-649e66b810d8' User entered 'None (0)'	System	03 Sep 2020 19:37:35
	System	03 Sep 2020 19:37:35

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:37:22', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cc9649bd-ab35-44d7-9a67-649e66b810d8' User entered 'None (0)'	System	03 Sep 2020 19:37:35
	System	03 Sep 2020 19:37:35

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:37:26', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cc9649bd-ab35-44d7-9a67-649e66b810d8' User entered 'No (N)'	System	03 Sep 2020 19:37:35
	System	03 Sep 2020 19:37:35

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-03T12:37:31', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cc9649bd-ab35-44d7-9a67-649e66b810d8' User entered '03 Sep 2020 12:37'	System	03 Sep 2020 19:37:35
	System	03 Sep 2020 19:37:35

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	29 Aug 2020 22:27:40
User entered 'Day 7'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:36', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '604d6f5f-3b69-41bb-a68f-4f80d1b33b96' User entered 'None (0)'	System	05 Sep 2020 01:01:09
	System	05 Sep 2020 01:01:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:40', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '604d6f5f-3b69-41bb-a68f-4f80d1b33b96' User entered 'None (0)'	System	05 Sep 2020 01:01:09
	System	05 Sep 2020 01:01:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:44', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '604d6f5f-3b69-41bb-a68f-4f80d1b33b96' User entered 'None (0)'	System	05 Sep 2020 01:01:09
	System	05 Sep 2020 01:01:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:48', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '604d6f5f-3b69-41bb-a68f-4f80d1b33b96' User entered 'None (0)'	System	05 Sep 2020 01:01:09
	System	05 Sep 2020 01:01:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:51', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '604d6f5f-3b69-41bb-a68f-4f80d1b33b96' User entered 'None (0)'	System	05 Sep 2020 01:01:09
	System	05 Sep 2020 01:01:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:54', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '604d6f5f-3b69-41bb-a68f-4f80d1b33b96' User entered 'None (0)'	System	05 Sep 2020 01:01:09
	System	05 Sep 2020 01:01:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:00:59', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '604d6f5f-3b69-41bb-a68f-4f80d1b33b96' User entered 'No (N)'	System	05 Sep 2020 01:01:09
	System	05 Sep 2020 01:01:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-09-04T18:01:04', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '604d6f5f-3b69-41bb-a68f-4f80d1b33b96' User entered '04 Sep 2020 18:01'	System	05 Sep 2020 01:01:09
	System	05 Sep 2020 01:01:09

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 22:27:40

US3192006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:39:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 22:27:40

US3192006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:42:13
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	08 Sep 2020 21:38:16

US3192006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:42:13
User entered '5 Sep 2020'	Saysamone Banks (b) (4) (b) (4)	08 Sep 2020 21:38:16

US3192006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:42:13
User entered 'Contact Made (CONTACT MADE)'	Saysamone Banks (b) (4) (b) (4)	08 Sep 2020 21:38:16

US3192006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:42:13
User entered empty.	Saysamone Banks (b) (4) (b) (4)	08 Sep 2020 21:38:16

US3192006

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:42:18
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	08 Sep 2020 21:39:04

US3192006

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'I'	System	08 Sep 2020 21:39:04

US3192006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:52:27
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	14 Sep 2020 22:08:46

US3192006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:52:27
User entered '14 Sep 2020'	Zoe Sesma (b) (4) (b) (4)	14 Sep 2020 22:08:46

US3192006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:52:27
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4) (b) (4)	14 Sep 2020 22:08:46

US3192006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:52:27
User entered empty.	Zoe Sesma (b) (4) (b) (4)	14 Sep 2020 22:08:46

US3192006

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:52:31
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	14 Sep 2020 22:08:51

US3192006

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'I'	System	14 Sep 2020 22:08:51

US3192006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:42:41
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	22 Sep 2020 22:09:03

US3192006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:42:41
User entered '22 Sep 2020'	Zoe Sesma (b) (4) (b) (4)	22 Sep 2020 22:09:03

US3192006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:42:41
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4) (b) (4)	22 Sep 2020 22:09:03

US3192006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:42:41
User entered empty.	Zoe Sesma (b) (4) (b) (4)	22 Sep 2020 22:09:03

US3192006

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:42:48
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	22 Sep 2020 22:09:07

US3192006

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'I'	System	22 Sep 2020 22:09:07

US3192006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:00
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:48:21

US3192006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:00
User entered '28 Sep 2020'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:48:21

US3192006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:00
User entered 'Clinic (Clinic)'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:48:21

US3192006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'VISIT3'	System	28 Sep 2020 17:48:21

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:45
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:45
User entered '28 Sep 2020'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:45
User entered '08:10'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered '28 Sep 2020 08:10'	System	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:45
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		01 Oct 2020 18:36:31
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Amanda Hermosillo (b) (4)	28 Sep 2020 17:50:46
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Sep 2020 17:49:22
User entered '96.3' F	Amanda Hermosillo (b) (4)	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:45
User entered 'Oral (Oral)'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:45
User entered empty.	Amanda Hermosillo (b) (4)	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:45
User entered '71'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'bpm'	System	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:45
User entered '16'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'breaths/min'	System	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:45
User entered '137'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'mmHg'	System	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:45
User entered '78'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'mmHg'	System	28 Sep 2020 17:49:22

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27

US3192006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27

US3192006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:53
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:48:31

US3192006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:43:53
User entered '28 Sep 2020'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:48:31

US3192006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:44:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:48:44

US3192006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:44:06
User entered '28 Sep 2020'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:48:44

US3192006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:44:06
User entered '08:25'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:48:44

US3192006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered '28 Sep 2020 08:25'	System	28 Sep 2020 17:48:44

US3192006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	13 Feb 2021 19:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:44:12
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	28 Sep 2020 17:50:53

US3192006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'I'	System	28 Sep 2020 17:50:53

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 64'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-10-03T10:00:57', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '5b384992-aecf-4933-95aa-53ef4d25c7fb' User entered 'No (N)'	System	03 Oct 2020 17:01:25
	System	03 Oct 2020 17:01:25

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you been exposed to someone with 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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-10-03T10:01:06', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '5b384992-aecf-4933-95aa-53ef4d25c7fb'	System	03 Oct 2020 17:01:25
User entered 'No (N)'	System	03 Oct 2020 17:01:25

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-10-03T10:01:11', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '5b384992-aecf-4933-95aa-53ef4d25c7fb' User entered '03 Oct 2020 10:01:11'	System	03 Oct 2020 17:01:25
	System	03 Oct 2020 17:01:25

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '01 Oct 2020 00:01'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '05 Oct 2020 23:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 71'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-10-08T19:48:03', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '5d7e79e2-319c-4cad-9ec2-6ecaf6bbdf64' User entered 'No (N)'	System	09 Oct 2020 02:48:15
	System	09 Oct 2020 02:48:15

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you been exposed to someone with 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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-10-08T19:48:09', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '5d7e79e2-319c-4cad-9ec2-6ecaf6bbdf64'	System	09 Oct 2020 02:48:15
User entered 'No (N)'	System	09 Oct 2020 02:48:15

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-10-08T19:48:13', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '5d7e79e2-319c-4cad-9ec2-6ecaf6bbdf64' User entered '08 Oct 2020 19:48:13'	System	09 Oct 2020 02:48:15
	System	09 Oct 2020 02:48:15

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '08 Oct 2020 00:01'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '12 Oct 2020 23:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 78'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-10-17T12:50:19', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '84fb8a65-4766-4a83-80aa-cc03012807d2'	System	17 Oct 2020 19:50:39
User entered 'No (N)'	System	17 Oct 2020 19:50:39

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-10-17T12:50:25', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '84fb8a65-4766-4a83-80aa-cc03012807d2'	System	17 Oct 2020 19:50:39
User entered 'No (N)'	System	17 Oct 2020 19:50:39

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-10-17T12:50:34', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '84fb8a65-4766-4a83-80aa-cc03012807d2' User entered '17 Oct 2020 12:50:34'	System	17 Oct 2020 19:50:39
	System	17 Oct 2020 19:50:39

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '15 Oct 2020 00:01'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '19 Oct 2020 23:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 92'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-10-31T12:44:37', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'b35a936b-052d-49f8-9734-8bc344d3274f' User entered 'No (N)'	System	31 Oct 2020 19:45:01
	System	31 Oct 2020 19:45:01

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-10-31T12:44:43', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'b35a936b-052d-49f8-9734-8bc344d3274f'	System	31 Oct 2020 19:45:01
User entered 'No (N)'	System	31 Oct 2020 19:45:01

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-10-31T12:44:57', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'b35a936b-052d-49f8-9734-8bc344d3274f' User entered '31 Oct 2020 12:44:57'	System	31 Oct 2020 19:45:01
	System	31 Oct 2020 19:45:01

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '29 Oct 2020 00:01'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '02 Nov 2020 23:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 99'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-11-05T15:19:44', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'b035f341-05c6-425f-940a-9f0dc61a3261' User entered 'No (N)'	System	05 Nov 2020 22:20:07
	System	05 Nov 2020 22:20:07

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you been exposed to someone with 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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-11-05T15:19:58', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'b035f341-05c6-425f-940a-9f0dc61a3261'	System	05 Nov 2020 22:20:07
User entered 'No (N)'	System	05 Nov 2020 22:20:07

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-11-05T15:20:04', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'b035f341-05c6-425f-940a-9f0dc61a3261' User entered '05 Nov 2020 15:20:04'	System	05 Nov 2020 22:20:07
	System	05 Nov 2020 22:20:07

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '05 Nov 2020 00:01'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '09 Nov 2020 23:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 106'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-11-12T06:40:32', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '90e81c97-8968-4f03-ab5b-3df9d934f986'	System	12 Nov 2020 13:40:53
User entered 'No (N)'	System	12 Nov 2020 13:40:53

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you been exposed to someone with 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)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-11-12T06:40:37', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '90e81c97-8968-4f03-ab5b-3df9d934f986'	System	12 Nov 2020 13:40:53
User entered 'No (N)'	System	12 Nov 2020 13:40:53

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-11-12T06:40:42', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '90e81c97-8968-4f03-ab5b-3df9d934f986' User entered '12 Nov 2020 06:40:42'	System	12 Nov 2020 13:40:53
	System	12 Nov 2020 13:40:53

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '12 Nov 2020 00:01'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:06:34
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '16 Nov 2020 23:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47
Data entry locked.	System	01 Aug 2020 21:18:40
User entered 'Day 113'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '19 Nov 2020 00:01'	System	01 Aug 2020 21:18:40

US3192006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:27:47
Data entry locked.	System	01 Aug 2020 21:18:40
User entered '23 Nov 2020 23:59'	System	01 Aug 2020 21:18:40

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-11-25T12:50:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'c6f7e3fb-511f-432d-843a-94057295a7c8'	System	25 Nov 2020 19:50:12
User entered 'No (N)'	System	25 Nov 2020 19:50:12

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-11-25T12:50:05', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'c6f7e3fb-511f-432d-843a-94057295a7c8'	System	25 Nov 2020 19:50:12
User entered 'No (N)'	System	25 Nov 2020 19:50:12

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-11-25T12:50:10', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'c6f7e3fb-511f-432d-843a-94057295a7c8'	System	25 Nov 2020 19:50:12
User entered '25 Nov 2020 12:50:10'	System	25 Nov 2020 19:50:12

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-04T13:39:59', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4a7e6f16-8399-41ed-8eda-1e1230d43c35'	System	04 Dec 2020 20:40:12
User entered 'No (N)'	System	04 Dec 2020 20:40:12

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-04T13:40:06', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4a7e6f16-8399-41ed-8eda-1e1230d43c35'	System	04 Dec 2020 20:40:12
User entered 'No (N)'	System	04 Dec 2020 20:40:12

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-04T13:40:10', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '4a7e6f16-8399-41ed-8eda-1e1230d43c35' User entered '04 Dec 2020 13:40:10'	System	04 Dec 2020 20:40:12
	System	04 Dec 2020 20:40:12

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-08T18:25:19', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '23844ace-1692-49e6-a41c-5f89811b788e' User entered 'No (N)'	System	09 Dec 2020 01:25:39
	System	09 Dec 2020 01:25:39

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-08T18:25:27', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '23844ace-1692-49e6-a41c-5f89811b788e' User entered 'No (N)'	System	09 Dec 2020 01:25:39

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-08T18:25:31', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '23844ace-1692-49e6-a41c-5f89811b788e' User entered '08 Dec 2020 18:25:31'	System	09 Dec 2020 01:25:39
	System	09 Dec 2020 01:25:39

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-14T07:21:24', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '8a053c1d-a9c8-42f1-9ceb-e476978fabbe' User entered 'No (N)'	System	14 Dec 2020 14:21:41
	System	14 Dec 2020 14:21:41

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-14T07:21:28', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '8a053c1d-a9c8-42f1-9ceb-e476978fabbe' User entered 'No (N)'	System	14 Dec 2020 14:21:41

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-14T07:21:37', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '8a053c1d-a9c8-42f1-9ceb-e476978fabbe' User entered '14 Dec 2020 07:21:37'	System	14 Dec 2020 14:21:41
	System	14 Dec 2020 14:21:41

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-21T08:33:30', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'adb10c59-3a3d-4696-ae34-697da62e186d' User entered 'No (N)'	System	21 Dec 2020 15:33:44
	System	21 Dec 2020 15:33:44

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-21T08:33:34', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'adb10c59-3a3d-4696-ae34-697da62e186d' User entered 'No (N)'	System	21 Dec 2020 15:33:44
	System	21 Dec 2020 15:33:44

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-21T08:33:39', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'adb10c59-3a3d-4696-ae34-697da62e186d' User entered '21 Dec 2020 08:33:39'	System	21 Dec 2020 15:33:44
	System	21 Dec 2020 15:33:44

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-28T07:29:49', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '68aa5df8-a8f5-4dde-aac9-ccd9e274880c' User entered 'No (N)'	System	28 Dec 2020 14:29:59
	System	28 Dec 2020 14:29:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-28T07:29:53', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '68aa5df8-a8f5-4dde-aac9-ccd9e274880c' User entered 'No (N)'	System	28 Dec 2020 14:29:59
	System	28 Dec 2020 14:29:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2020-12-28T07:29:57', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '68aa5df8-a8f5-4dde-aac9-ccd9e274880c' User entered '28 Dec 2020 07:29:57'	System	28 Dec 2020 14:29:59
	System	28 Dec 2020 14:29:59

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-01-05T16:57:13', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '011efb4c-5d22-4e41-8e92-0af0d29a9f04'	System	05 Jan 2021 23:57:30
User entered 'No (N)'	System	05 Jan 2021 23:57:30

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-01-05T16:57:21', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '011efb4c-5d22-4e41-8e92-0af0d29a9f04'	System	05 Jan 2021 23:57:30
User entered 'No (N)'	System	05 Jan 2021 23:57:30

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-01-05T16:57:25', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '011efb4c-5d22-4e41-8e92-0af0d29a9f04' User entered '05 Jan 2021 16:57:25'	System	05 Jan 2021 23:57:30
	System	05 Jan 2021 23:57:30

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-01-11T00:38:51', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cd0f80ab-96d7-4d97-87df-517876b35ff8'	System	11 Jan 2021 07:39:11
User entered 'No (N)'	System	11 Jan 2021 07:39:11

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-01-11T00:39:02', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cd0f80ab-96d7-4d97-87df-517876b35ff8'	System	11 Jan 2021 07:39:11
User entered 'No (N)'	System	11 Jan 2021 07:39:11

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-01-11T00:39:08', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'cd0f80ab-96d7-4d97-87df-517876b35ff8' User entered '11 Jan 2021 00:39:08'	System	11 Jan 2021 07:39:11
	System	11 Jan 2021 07:39:11

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-01-21T17:59:40', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '69c6ecf2-b1c6-4580-aeef-f2224daff0f6'	System	22 Jan 2021 00:59:57
User entered 'No (N)'	System	22 Jan 2021 00:59:57

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-01-21T17:59:51', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '69c6ecf2-b1c6-4580-aeef-f2224daff0f6'	System	22 Jan 2021 00:59:57
User entered 'No (N)'	System	22 Jan 2021 00:59:57

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-01-21T17:59:55', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '69c6ecf2-b1c6-4580-aeef-f2224daff0f6'	System	22 Jan 2021 00:59:57
User entered '21 Jan 2021 17:59:55'	System	22 Jan 2021 00:59:57

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-01-25T06:57:49', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ac7c0531-c7a2-4736-8706-d0610bc1e12d' User entered 'No (N)'	System	25 Jan 2021 13:58:11

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-01-25T06:57:59', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ac7c0531-c7a2-4736-8706-d0610bc1e12d' User entered 'No (N)'	System	25 Jan 2021 13:58:11

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-01-25T06:58:06', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ac7c0531-c7a2-4736-8706-d0610bc1e12d' User entered '25 Jan 2021 06:58:06'	System	25 Jan 2021 13:58:11

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-02-01T08:13:05', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'bb41ffaf-7e4c-40c0-91cb-723427b1319d' User entered 'No (N)'	System	01 Feb 2021 15:13:16
	System	01 Feb 2021 15:13:16

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-02-01T08:13:09', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'bb41ffaf-7e4c-40c0-91cb-723427b1319d'	System	01 Feb 2021 15:13:16
User entered 'No (N)'	System	01 Feb 2021 15:13:16

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-02-01T08:13:13', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'bb41ffaf-7e4c-40c0-91cb-723427b1319d'	System	01 Feb 2021 15:13:16
User entered '01 Feb 2021 08:13:13'	System	01 Feb 2021 15:13:16

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-02-11T18:00:45', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ac42f1f6-c691-45ed-8936-de33cd937c2f' User entered 'No (N)'	System	12 Feb 2021 01:01:54
	System	12 Feb 2021 01:01:54

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-02-11T18:00:50', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ac42f1f6-c691-45ed-8936-de33cd937c2f' User entered 'No (N)'	System	12 Feb 2021 01:01:54

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-02-11T18:00:59', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ac42f1f6-c691-45ed-8936-de33cd937c2f' User entered '11 Feb 2021 18:00:59'	System	12 Feb 2021 01:01:54
	System	12 Feb 2021 01:01:54

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-02-18T17:59:26', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '29b06bc8-2c6b-4fc8-b1ac-c6735b849dd0' User entered 'No (N)'	System	19 Feb 2021 00:59:43
	System	19 Feb 2021 00:59:43

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-02-18T17:59:32', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '29b06bc8-2c6b-4fc8-b1ac-c6735b849dd0' User entered 'No (N)'	System	19 Feb 2021 00:59:43

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-02-18T17:59:38', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '29b06bc8-2c6b-4fc8-b1ac-c6735b849dd0' User entered '18 Feb 2021 17:59:38'	System	19 Feb 2021 00:59:43
	System	19 Feb 2021 00:59:43

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-02-22T07:23:38', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '889cacb5-a7cb-4bca-b075-f7771026f97b' User entered 'No (N)'	System	22 Feb 2021 14:23:48
	System	22 Feb 2021 14:23:48

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-02-22T07:23:42', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '889cacb5-a7cb-4bca-b075-f7771026f97b' User entered 'No (N)'	System	22 Feb 2021 14:23:48

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-02-22T07:23:45', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '889cacb5-a7cb-4bca-b075-f7771026f97b' User entered '22 Feb 2021 07:23:45'	System	22 Feb 2021 14:23:48
	System	22 Feb 2021 14:23:48

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-01T07:54:12-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f5903822-b36e-4b21-8e44-a04eb96759fd'	System	01 Mar 2021 14:54:26
User entered 'No (N)'	System	01 Mar 2021 14:54:26

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-01T07:54:18-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f5903822-b36e-4b21-8e44-a04eb96759fd'	System	01 Mar 2021 14:54:26
User entered 'No (N)'	System	01 Mar 2021 14:54:26

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-01T07:54:22-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f5903822-b36e-4b21-8e44-a04eb96759fd' User entered '01 Mar 2021 14:54:22'	System	01 Mar 2021 14:54:26
	System	01 Mar 2021 14:54:26

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-10T12:00:28-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f0e940cb-d0a4-4adb-8be1-1943d3aec09c'	System	10 Mar 2021 19:00:40
User entered 'No (N)'	System	10 Mar 2021 19:00:40

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-10T12:00:32-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f0e940cb-d0a4-4adb-8be1-1943d3aec09c'	System	10 Mar 2021 19:00:40
User entered 'No (N)'	System	10 Mar 2021 19:00:40

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-10T12:00:36-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'f0e940cb-d0a4-4adb-8be1-1943d3aec09c' User entered '10 Mar 2021 12:00:36'	System	10 Mar 2021 19:00:40
	System	10 Mar 2021 19:00:40

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-15T07:09:53-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'e7e00d1e-5598-464a-babd-810d87bef8f1'	System	15 Mar 2021 14:10:05
User entered 'No (N)'	System	15 Mar 2021 14:10:05

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-15T07:09:57-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'e7e00d1e-5598-464a-babd-810d87bef8f1'	System	15 Mar 2021 14:10:05
User entered 'No (N)'	System	15 Mar 2021 14:10:05

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-15T07:10:00-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'e7e00d1e-5598-464a-babd-810d87bef8f1'	System	15 Mar 2021 14:10:05
User entered '15 Mar 2021 07:10:00'	System	15 Mar 2021 14:10:05

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-29T07:37:45-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ce0c5c95-3afe-4c8d-aca3-9f11e9cf43db' User entered 'No (N)'	System	05 Apr 2021 14:02:12
	System	05 Apr 2021 14:02:12

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-29T07:37:49-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ce0c5c95-3afe-4c8d-aca3-9f11e9cf43db' User entered 'No (N)'	System	05 Apr 2021 14:02:12

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-29T07:37:54-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ce0c5c95-3afe-4c8d-aca3-9f11e9cf43db' User entered '29 Mar 2021 07:37:54'	System	05 Apr 2021 14:02:12

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-04-05T07:02:01-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '128b7200-3c17-4002-8334-07c876e4f488'	System	05 Apr 2021 14:02:12
User entered 'No (N)'	System	05 Apr 2021 14:02:12

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-04-05T07:02:05-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '128b7200-3c17-4002-8334-07c876e4f488'	System	05 Apr 2021 14:02:12
User entered 'No (N)'	System	05 Apr 2021 14:02:12

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-04-05T07:02:09-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '128b7200-3c17-4002-8334-07c876e4f488'	System	05 Apr 2021 14:02:12
User entered '05 Apr 2021 07:02:09'	System	05 Apr 2021 14:02:12

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-04-12T08:19:55-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '08fc16ad-b2b7-4592-8717-eb9f1a4365d6'	System	12 Apr 2021 15:20:08
User entered 'No (N)'	System	12 Apr 2021 15:20:08

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-04-12T08:19:58-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '08fc16ad-b2b7-4592-8717-eb9f1a4365d6'	System	12 Apr 2021 15:20:08
User entered 'No (N)'	System	12 Apr 2021 15:20:08

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-04-12T08:20:01-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '08fc16ad-b2b7-4592-8717-eb9f1a4365d6'	System	12 Apr 2021 15:20:08
User entered '12 Apr 2021 08:20:01'	System	12 Apr 2021 15:20:08

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-04-19T16:42:30-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '7f9016e0-2d4d-4149-b63d-789267a61cc8'	System	19 Apr 2021 23:42:40
User entered 'No (N)'	System	19 Apr 2021 23:42:40

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-04-19T16:42:32-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '7f9016e0-2d4d-4149-b63d-789267a61cc8'	System	19 Apr 2021 23:42:40
User entered 'No (N)'	System	19 Apr 2021 23:42:40

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-04-19T16:42:35-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '7f9016e0-2d4d-4149-b63d-789267a61cc8'	System	19 Apr 2021 23:42:40
User entered '19 Apr 2021 16:42:35'	System	19 Apr 2021 23:42:40

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-04-28T12:00:43-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ef600b37-00ca-447a-ae6f-ab42f63460dd' User entered 'No (N)'	System	28 Apr 2021 23:19:13
	System	28 Apr 2021 23:19:13

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-04-28T12:00:46-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ef600b37-00ca-447a-ae6f-ab42f63460dd' User entered 'No (N)'	System	28 Apr 2021 23:19:13
	System	28 Apr 2021 23:19:13

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-04-28T12:00:49-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: 'ef600b37-00ca-447a-ae6f-ab42f63460dd' User entered '28 Apr 2021 12:00:49'	System	28 Apr 2021 23:19:13
	System	28 Apr 2021 23:19:13

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-05-03T09:32:08-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9899ee25-db9d-45df-88ef-2ad7b2180aea'	System	03 May 2021 16:32:19
User entered 'No (N)'	System	03 May 2021 16:32:19

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

Have you been exposed to someone with 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 (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-05-03T09:32:10-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9899ee25-db9d-45df-88ef-2ad7b2180aea'	System	03 May 2021 16:32:19
User entered 'No (N)'	System	03 May 2021 16:32:19

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-05-03T09:32:14-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '9899ee25-db9d-45df-88ef-2ad7b2180aea' User entered '03 May 2021 09:32:14'	System	03 May 2021 16:32:19
	System	03 May 2021 16:32:19

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 11:27:47

US3192006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:27:47
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 11:27:47

US3192006

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:39:06

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-01T07:54:40-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '35b242bc-b97e-45c0-9d00-aeb5433540f5'	System	01 Mar 2021 14:54:54
User entered 'No (N)'	System	01 Mar 2021 14:54:54

US3192006

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:39:06

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:19:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (36B2538B-EF60-422E-82E1-AC08247C61FD)', Time: '2021-03-01T07:54:52-07:00', User OID: 'PatientReportedOutcome (US3192006)', ODM File OID: '35b242bc-b97e-45c0-9d00-aeb5433540f5' User entered '01 Mar 2021 14:54:52'	System	01 Mar 2021 14:54:54
	System	01 Mar 2021 14:54:54

US3192006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:48:32
User entered 'Yes (Y)'		27 Oct 2020 15:47:45

US3192006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:48:32
User entered '26 Oct 2020'		27 Oct 2020 15:47:45

US3192006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:48:32
User entered 'Contact Made (CONTACT MADE)'		27 Oct 2020 15:47:45

US3192006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:48:32
User entered empty.		27 Oct 2020 15:47:45

US3192006

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:48:35
User entered 'Yes (Y)'		27 Oct 2020 15:47:31

US3192006

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:30:27
User entered 'I'	System	27 Oct 2020 15:47:31

US3192006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:14:37
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	01 Dec 2020 17:02:57

US3192006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:14:37
User entered '30 Nov 2020'	Amanda Hermosillo (b) (4)	01 Dec 2020 17:02:57

US3192006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:14:37
User entered 'Contact Made (CONTACT MADE)'	Amanda Hermosillo (b) (4)	01 Dec 2020 17:02:57

US3192006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:14:37
User entered empty.	Amanda Hermosillo (b) (4)	01 Dec 2020 17:02:57

US3192006

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:14:41
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	01 Dec 2020 17:03:04

US3192006

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User entered 'I'	System	01 Dec 2020 17:03:04

US3192006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:13:27
User entered 'Yes (Y)'		30 Dec 2020 01:31:26

US3192006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:13:27
User entered '29 Dec 2020'		30 Dec 2020 01:31:26

US3192006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:13:27
User entered 'Contact Made (CONTACT MADE)'		30 Dec 2020 01:31:26

US3192006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:13:27
User entered empty.		30 Dec 2020 01:31:26

US3192006

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:13:30
User entered 'Yes (Y)'		30 Dec 2020 01:31:34

US3192006

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User entered 'I'	System	30 Dec 2020 01:31:34

US3192006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
DataPoint Verified.		15 Mar 2021 23:33:22
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	27 Jan 2021 23:01:46

US3192006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
DataPoint Verified.		15 Mar 2021 23:33:22
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '27 Jan 2021'	(b) (4) maggie Tono (b) (4) (b) (4)	27 Jan 2021 23:01:46

US3192006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
DataPoint Verified.		15 Mar 2021 23:33:22
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) maggie Tono (b) (4) (b) (4)	27 Jan 2021 23:01:46

US3192006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
DataPoint Verified.		15 Mar 2021 23:33:22
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	27 Jan 2021 23:01:46

US3192006

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
DataPoint Verified.		15 Mar 2021 23:33:26
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	27 Jan 2021 23:01:34

US3192006

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:47:45
User entered 'I'	System	27 Jan 2021 23:01:34

US3192006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 00:19:46
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	02 Mar 2021 22:44:50

US3192006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 00:19:46
User entered '2 Mar 2021'	Zoe Sesma (b) (4) (b) (4)	02 Mar 2021 22:44:50

US3192006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 00:19:46
User entered 'Clinic (Clinic)'	Zoe Sesma (b) (4) (b) (4)	02 Mar 2021 22:44:50

US3192006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User entered 'VISIT4'	System	02 Mar 2021 22:44:50

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
DataPoint Verified.		21 Apr 2021 18:30:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
DataPoint Verified.		21 Apr 2021 18:30:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
DataPoint Verified.		21 Apr 2021 18:30:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
User entered '15:11'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User entered '02 Mar 2021 15:11'	System	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
DataPoint Verified.		21 Apr 2021 18:30:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
DataPoint Verified.		21 Apr 2021 18:30:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
DataPoint Verified.		21 Apr 2021 18:30:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
DataPoint Verified.		21 Apr 2021 18:30:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
User entered '66'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User entered 'bpm'	System	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
DataPoint Verified.		21 Apr 2021 18:30:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User entered 'breaths/min'	System	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
DataPoint Verified.		21 Apr 2021 18:30:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
User entered '132'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User entered 'mmHg'	System	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
DataPoint Verified.		21 Apr 2021 18:30:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
User entered '74'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User entered 'mmHg'	System	02 Apr 2021 16:48:10

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24

US3192006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24

US3192006

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 00:19:51
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	02 Mar 2021 22:44:54

US3192006

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 00:19:51
User entered '2 Mar 2021'	Zoe Sesma (b) (4) (b) (4)	02 Mar 2021 22:44:54

US3192006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 00:20:00
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	02 Mar 2021 22:45:01

US3192006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 00:20:00
User entered '2 Mar 2021'	Zoe Sesma (b) (4) (b) (4)	02 Mar 2021 22:45:01

US3192006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 00:20:00
User entered '15:16'	Zoe Sesma (b) (4) (b) (4)	02 Mar 2021 22:45:01

US3192006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User entered '2 Mar 2021 15:16'	System	02 Mar 2021 22:45:01

US3192006

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 00:20:03
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	02 Mar 2021 22:45:04

US3192006

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:19:24
User entered 'I'	System	02 Mar 2021 22:45:04

US3192006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:29
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:48:57
User entered 'Yes (Y)'	Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 17:52:42

US3192006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:29
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:48:57
User entered '29 Mar 2021'	Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 17:52:42

US3192006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:29
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:48:57
User entered 'Contact Made (CONTACT MADE)'	Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 17:52:42

US3192006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:29
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:48:57
User entered empty.	Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 17:52:42

US3192006

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:29
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:49:25
User entered 'Yes (Y)'	Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 17:52:46

US3192006

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:29
User entered 'I'	System	30 Mar 2021 17:52:46

US3192006

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

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		15 Mar 2021 23:33:41
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered 'Yes (Y)'	(b) (4)	
	Zoe Sesma (b) (4)	07 Jan 2021 15:18:52
	(b) (4)	

US3192006

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

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:46:07
User entered '6 Jan 2021' reason for change: Data Entry Error		25 Mar 2021 23:47:33
DataPoint Un-verified.		18 Mar 2021 20:38:55
Signature has been broken.		18 Mar 2021 20:38:55
User entered '7 Jan 2021' reason for change: Data Entry Error		18 Mar 2021 20:38:55
DataPoint Verified.		15 Mar 2021 23:33:41
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '6 Jan 2021'	(b) (4) Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 15:18:52

US3192006

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

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		15 Mar 2021 23:33:41
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered 'Clinic (Clinic)'	(b) (4) Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 15:18:52

US3192006

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

Form: Visit Date

Generated On: 09 Jun 2021 15:39:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
User entered 'UNBLND_DECIDE'	System	07 Jan 2021 15:18:52

US3192006

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

Form: Unblinding

Generated On: 09 Jun 2021 15:39:06

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:46:13
User entered '6 Jan 2021' reason for change: Data Entry Error		25 Mar 2021 23:47:45
DataPoint Un-verified.		18 Mar 2021 20:34:32
Signature has been broken.		18 Mar 2021 20:34:32
User entered '7 Jan 2021' reason for change: Data Entry Error		18 Mar 2021 20:34:32
DataPoint Verified.		16 Mar 2021 00:11:17
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '6 Jan 2021'	(b) (4) Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 15:19:04

US3192006

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

Form: Unblinding

Generated On: 09 Jun 2021 15:39:06

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:46:15
User entered '0'		18 Mar 2021 20:34:32
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:08:10

US3192006

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

Form: Unblinding

Generated On: 09 Jun 2021 15:39:06

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		16 Mar 2021 00:11:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered 'Yes (Y)'	(b) (4) Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 15:19:04

US3192006

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

Form: Unblinding

Generated On: 09 Jun 2021 15:39:06

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:23:45
User closed query 'Please specify protocol participant was unblinded under.' (Site from CRA).		25 Mar 2021 17:23:34
Query 'Please specify protocol participant was unblinded under.' answered with 'updated' (Site from CRA).		25 Mar 2021 17:07:07
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error		25 Mar 2021 17:06:37
User opened query 'Please specify protocol participant was unblinded under.' (Site from CRA).		25 Mar 2021 15:41:43
User entered empty.		18 Mar 2021 20:34:32
Amendment Manager inserted this DataPoint.		06 Mar 2021 11:08:10
	System	

US3192006

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

Form: Unblinding

Generated On: 09 Jun 2021 15:39:06

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		26 Apr 2021 21:49:23
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:17:07
User closed query 'Per IRT: "According to IRT assignment unblinding was completed on 7Jan21. As per the memo sent to sites regarding Unblinding eCRF instructions on 13Apr dated 7Apr, this date must be the date the transaction happened in IRT. Please enter the unblinding date per IRT."' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:06:52
Query 'Per IRT: "According to IRT assignment unblinding was completed on 7Jan21. As per the memo sent to sites regarding Unblinding eCRF instructions on 13Apr dated 7Apr, this date must be the date the transaction happened in IRT. Please enter the unblinding date per IRT."' answered with 'update as is on the irt ' (Site from DM).	maggie Tono (b) (4) (b) (4)	22 Apr 2021 15:43:13
DataPoint Un-verified.	maggie Tono (b) (4) (b) (4)	22 Apr 2021 15:42:42
Signature has been broken.	maggie Tono (b) (4) (b) (4)	22 Apr 2021 15:42:42
User entered '7 Jan 2021' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	22 Apr 2021 15:42:42
User opened query 'Per IRT: "According to IRT assignment unblinding was completed on 7Jan21. As per the memo sent to sites regarding Unblinding eCRF instructions on 13Apr dated 7Apr, this date must be the date the transaction happened in IRT. Please enter the unblinding date per IRT."' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 05:15:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:46:23
DataPoint Un-verified.		25 Mar 2021 23:47:45
User entered '6 Jan 2021' reason for change: Data Entry Error		25 Mar 2021 23:47:45
DataPoint Verified.		25 Mar 2021 15:40:31

US3192006

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

Form: Unblinding

Generated On: 09 Jun 2021 15:39:06

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per IRT date of unblinding was 7Jan2021. Please explain how this is possible and reconcile data as needed. Thanks' (Site from CRA). Query 'Per IRT date of unblinding was 7Jan2021. Please explain how this is possible and reconcile data as needed. Thanks' answered with 'updated' (Site from CRA). Signature has been broken.	(b) (4), (b) (6)	25 Mar 2021 15:40:21
		18 Mar 2021 20:35:05
		18 Mar 2021 20:34:32
User entered '7 Jan 2021' reason for change: Data Entry Error		18 Mar 2021 20:34:32
User opened query 'Per IRT date of unblinding was 7Jan2021. Please explain how this is possible and reconcile data as needed. Thanks' (Site from CRA). User signature succeeded.		16 Mar 2021 00:11:50
	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '6 Jan 2021'	Zoe Sesma (b) (4)	07 Jan 2021 15:19:04
	(b) (4)	

US3192006

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

Form: Unblinding

Generated On: 09 Jun 2021 15:39:06

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		16 Mar 2021 00:11:56
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 15:19:04

US3192006

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

Form: Unblinding

Generated On: 09 Jun 2021 15:39:06

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		16 Mar 2021 00:11:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 11:12:38
User entered 'mRNA-1273 (mRNA-1273)'	Zoe Sesma (b) (4)	07 Jan 2021 15:19:04
	(b) (4)	

US3192006

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

Form: Unblinding

Generated On: 09 Jun 2021 15:39:06

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		16 Mar 2021 00:11:59
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 11:12:38
User entered 'mRNA-1273 (mRNA-1273)'	Zoe Sesma (b) (4)	07 Jan 2021 15:19:04
	(b) (4)	

US3192006

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

Form: Unblinding

Generated On: 09 Jun 2021 15:39:06

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		16 Mar 2021 00:12:11
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered 'No (N)'	(b) (4)	
	Zoe Sesma (b) (4)	07 Jan 2021 15:19:04
	(b) (4)	

US3192006

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

Form: Unblinding

Generated On: 09 Jun 2021 15:39:06

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
User entered empty.	System	07 Jan 2021 15:19:04

US3192006

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

Form: Unblinding

Generated On: 09 Jun 2021 15:39:06

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
User entered empty.	System	07 Jan 2021 15:19:04

US3192006

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		16 Mar 2021 00:12:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered 'Yes (Y)'	(b) (4) Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 15:19:23

US3192006

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:46:37
User entered '6 Jan 2021' reason for change: Data Entry Error		25 Mar 2021 23:47:56
User closed query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	System	18 Mar 2021 20:36:13
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 20:36:13
Signature has been broken.		18 Mar 2021 20:36:13
User entered '7 Jan 2021' reason for change: Data Entry Error		18 Mar 2021 20:36:13
User opened query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	System	18 Mar 2021 20:34:32
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:12:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '6 Jan 2021'	(b) (4) Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 15:19:23

US3192006

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		16 Mar 2021 00:12:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '16:10'	(b) (4)	
	Zoe Sesma (b) (4)	07 Jan 2021 15:19:23
	(b) (4)	

US3192006

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
User entered '6 Jan 2021 16:10'	System	25 Mar 2021 23:47:56
User entered '7 Jan 2021 16:10'	System	18 Mar 2021 20:36:13
User entered '6 Jan 2021 16:10'	System	07 Jan 2021 15:19:23

US3192006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:39:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		16 Mar 2021 00:12:29
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered 'Yes (Y)'	(b) (4) Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 15:19:34

US3192006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:39:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "07-JAN-2021" is recorded under Participant Decision Visit / OL-D1 visit in EDC; however, in PPD portal, it is recorded as "06-JAN -2021" for OL-1 visit. Kindly review the collection date and update EDC or Preclarus portal as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 10:34:41
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:46:55
User closed query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	25 Mar 2021 23:47:45
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "07-JAN-2021" is recorded under Participant Decision Visit / OL-D1 visit in EDC; however, in PPD portal, it is recorded as "06-JAN -2021" for OL-1 visit. Kindly review the collection date and update EDC or Preclarus portal as appropriate, else clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 17:10:00
User opened query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	25 Mar 2021 17:09:41
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 17:09:41
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "07-JAN-2021" is recorded under Participant Decision Visit / OL-D1 visit in EDC; however, in PPD portal, it is recorded as "06-JAN -2021" for OL-1 visit. Kindly review the collection date and update EDC or Preclarus portal as appropriate, else clarify.' (Site from DM).		25 Mar 2021 08:05:00
User closed query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	18 Mar 2021 20:37:50
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 20:37:50
Signature has been broken.		18 Mar 2021 20:37:50

US3192006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:39:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '7 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 20:37:50
User opened query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	18 Mar 2021 20:34:32
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:12:29
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 07JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 08:28:25
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 07JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'PPD has a collection date of 06jan2021 in preclarus ' (Site from DM).	Yvonne De Los Reyes (b) (4)	10 Feb 2021 16:01:42
User entered '6 Jan 2021' reason for change: Data Entry Error	maggie Tono (b) (4)	05 Feb 2021 23:45:59
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 07JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 11:30:05
User entered '7 Jan 2021'	Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 15:19:34

US3192006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:39:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		16 Mar 2021 00:12:29
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '16:15'	(b) (4) Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 15:19:34

US3192006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:39:06

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
User entered '06 Jan 2021 16:15'	System	25 Mar 2021 17:09:41
User entered '7 Jan 2021 16:15'	System	18 Mar 2021 20:37:50
User entered '6 Jan 2021 16:15'	System	05 Feb 2021 23:45:59
User entered '7 Jan 2021 16:15'	System	07 Jan 2021 15:19:34

US3192006

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:39:06

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:12:49
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Query 'Please review 'hyperkalemia' noted in source and add as SAE/AE as applicable. Thanks' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:45:56
Query 'Please review source and confirm if 'acute renal failure' and 'chronic kidney disease' are adverse events or medical history and record in RAVE as appropriate. Thanks' canceled (Site from CRA).		21 Jan 2021 16:45:52
User opened query 'Please review 'hyperkalemia' noted in source and add as SAE/AE as applicable. Thanks' (Site from CRA).		20 Jan 2021 17:09:23
User opened query 'Please review source and confirm if 'acute renal failure' and 'chronic kidney disease' are adverse events or medical history and record in RAVE as appropriate. Thanks' (Site from CRA).		20 Jan 2021 17:08:23
DataPoint Verified.		30 Oct 2020 18:24:29
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	30 Aug 2020 20:49:53

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:43:00
Reviewed for Safety.		31 Aug 2020 15:04:21
User entered 'USA-US097-2020-mRNA-1273-P301000001'	System	31 Aug 2020 15:04:09
User entered 'New'	(b) (4), (b) (6)	31 Aug 2020 15:04:09

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 17:59:36
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\23.0.	Coder Import (b) (4)	07 Sep 2020 19:25:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Sep 2020 19:25:47
Data point term sent to Coder	System	07 Sep 2020 19:25:26
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	07 Sep 2020 19:25:01
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'updated' (Site from System).	maggie Tono (b) (4)	07 Sep 2020 19:25:01
	(b) (4)	
User entered 'DEHYDRATION' reason for change: Data Entry Error	maggie Tono (b) (4)	07 Sep 2020 19:24:51
	(b) (4)	
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	31 Aug 2020 14:26:33
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 01:45:48
User entered 'Dehydration and Hypotension'	Yvonne De Los Reyes	31 Aug 2020 01:44:52
	(b) (4)	

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 03:44:28
User closed query 'Per source response to this question is 'Y'. Please reconcile. Thanks' (Site from CRA).		15 Jan 2021 03:44:12
Query 'Per source response to this question is 'Y'. Please reconcile. Thanks' answered with 'Field has been updated to match source' (Site from CRA).	Saysamone Banks (b) (4)	07 Dec 2020 20:24:07
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 20:23:48
User opened query 'Per source response to this question is 'Y'. Please reconcile. Thanks' (Site from CRA).		23 Nov 2020 19:29:54
User closed query 'Per source field is not completed for medically-attended AE. Please reconcile. Thanks' (Site from CRA).		20 Nov 2020 03:40:34
Query 'Per source field is not completed for medically-attended AE. Please reconcile. Thanks' answered with 'CORRECT. QUERY HAS BEEN RESOLVED.' (Site from CRA).	Crystal Mata (b) (4)	18 Nov 2020 01:32:36
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	10 Nov 2020 21:49:56
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:01:36
DataPoint Verified.		30 Oct 2020 18:01:35
User opened query 'Per source field is not completed for medically-attended AE. Please reconcile. Thanks' (Site from CRA).		30 Oct 2020 18:00:58
DataPoint Un-verified.		30 Oct 2020 18:00:21
DataPoint Verified.		30 Oct 2020 17:59:40
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:42
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:01:40
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:01:45
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).		11 Sep 2020 16:13:40
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	31 Aug 2020 01:44:52
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:01:53
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Sep 2020 23:58:09
User entered empty; reason for change Data Entry Error	maggie Tono (b) (4) (b) (4)	30 Sep 2020 23:58:09
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Sep 2020 23:57:14
User entered '14:44' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	30 Sep 2020 23:57:14
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 23:58:09
User entered '16 Aug 2020 14:44'	System	30 Sep 2020 23:57:14
User entered empty.	System	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:01:51
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:01:50
User entered '17 Aug 2020'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:01:55
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

Severity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 03:45:02
User closed query 'Per source grade now appears to be '4'. Please reconcile. thanks. ' (Site from CRA).		15 Jan 2021 03:44:51
User closed query 'PV Query: Please confirm severity as grade 2/moderate for event of dehydration as event caused hospitalization. Please consider updating severity to grade 4.' (Site from Safety).		08 Dec 2020 20:50:35
Query 'PV Query: Please confirm severity as grade 2/moderate for event of dehydration as event caused hospitalization. Please consider updating severity to grade 4.' answered with 'Severity has been updated to grade 4' (Site from Safety).	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 20:25:47
Query 'Per source grade now appears to be '4'. Please reconcile. thanks. ' answered with 'Field has been updated to match source' (Site from CRA).	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 20:25:18
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 20:23:48
User opened query 'PV Query: Please confirm severity as grade 2/moderate for event of dehydration as event caused hospitalization. Please consider updating severity to grade 4.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:17:03
User opened query 'Per source grade now appears to be '4'. Please reconcile. thanks. ' (Site from CRA).		23 Nov 2020 19:30:53
User closed query 'Per source field is not completed for severity. Please reconcile. Thanks' (Site from CRA).		23 Nov 2020 19:30:22
Query 'Per source field is not completed for severity. Please reconcile. Thanks' answered with 'source updated ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:11:23
User opened query 'Per source field is not completed for severity. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:02:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:29:39
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:28:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Sep 2020 19:28:43

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	maggie Tono (b) (4)	07 Sep 2020 19:28:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 01:44:52
User entered empty.	System	31 Aug 2020 01:44:52
	Yvonne De Los Reyes	31 Aug 2020 01:44:52
	(b) (4)	

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:02:26
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:02:28
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:02:30
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:02:32
User entered 'I'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:02:34
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:02:37
User entered '17 Aug 2020'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:02:54
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:02:57
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:03:00
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:03:02
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:03:03
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:03:13
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).		13 Sep 2020 00:50:00
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:28:11
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:27:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Sep 2020 19:27:49
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:27:49
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	31 Aug 2020 15:03:13
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 01:44:52
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

US3192006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:39:54
User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' (Site from Safety).		21 Jan 2021 15:52:25
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' answered with 'updated ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:25:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:25:27
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 19:55:26
DataPoint Un-verified.	Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 19:54:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 19:54:19
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 18:30:49
User closed query 'PV Query: Please clarify the rationale why the event dehydration was assessed as not applicable to study procedure.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 21:13:24
Query 'PV Query: Please clarify the rationale why the event dehydration was assessed as not applicable to study procedure.' answered with 'No study procedure done' (Site from Safety).	Yvonne De Los Reyes (b) (4)	26 Dec 2020 22:06:33

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify the rationale why the event dehydration was assessed as not applicable to study procedure.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 20:05:50
		23 Nov 2020 19:31:04
User closed query 'This information is not documented in the source. Please reconcile. thanks' (Site from CRA).		23 Nov 2020 19:31:01
Query 'This information is not documented in the source. Please reconcile. thanks' answered with 'NA, not in source ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:11:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:11:37
User opened query 'This information is not documented in the source. Please reconcile. thanks' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:03:36
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:27:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Sep 2020 19:27:49
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:27:49
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 01:44:52
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:03:39
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:03:43
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		07 Sep 2020 19:30:29
User entered '0' reason for change: Data Entry Error	maggie Tono (b) (4)	07 Sep 2020 19:30:29
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	31 Aug 2020 01:44:52
User entered '1'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is no CM with direct verbatim during this hospitalization timeframe. Please review and ensure that the treatment given for this AE is recorded in the CM eCRF. Otherwise, update this field as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:03:17
Query 'Per DM CLR - RQ: Site's response noted. However, there is no CM with direct verbatim during this hospitalization timeframe. Please review and ensure that the treatment given for this AE is recorded in the CM eCRF. Otherwise, update this field as appropriate. ' answered with 'updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:25:51
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is no CM with direct verbatim during this hospitalization timeframe. Please review and ensure that the treatment given for this AE is recorded in the CM eCRF. Otherwise, update this field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 06:38:39
User closed query 'Per DM CLR: RQ: Response noted, however, there is no medication with this AE term as indication. Please update the medication's indication to include this AE and/or add any medication used. Otherwise, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:47:11
DataPoint Verified.		12 Nov 2020 18:58:24
Query 'Per DM CLR: RQ: Response noted, however, there is no medication with this AE term as indication. Please update the medication's indication to include this AE and/or add any medication used. Otherwise, clarify in query response.' answered with 'A current con med dose was reduced due to AE.' (Site from DM).	Yvonne De Los Reyes (b) (4)	10 Nov 2020 21:49:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: RQ: Response noted, however, there is no medication with this AE term as indication. Please update the medication's indication to include this AE and/or add any medication used. Otherwise, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 14:06:19
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	06 Oct 2020 02:31:08
' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	maggie Tono (b) (4) (b) (4)	24 Sep 2020 17:11:25
' answered with 'updated' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	23 Sep 2020 05:38:43
' (Site from DM). User entered 'I'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:57:52
DataPoint Un-verified.		30 Oct 2020 18:04:28
DataPoint Verified.		30 Oct 2020 18:04:27
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:04:34
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:08
User entered 'PATIENT WAS GOLFING IN 100 DEGREE TEMPERATURE AND BECAME DIZZY FOLLOWED BY BRIEF LOC. TAKEN TO HOSPITAL AND ADMITTED FOR DEHYDRATION AND HYPOTENSION. LISINOPRIL 40MG QD TAKEN SINCE 2012 WAS DECREASED TO 20MG QD. HOSPITAL RECORDS REQUESTED AND PENDING AT TIME OF REPORT. PT WAS DISCHARGED HOME W/O SEQUELAE ON 17AUG2020. his temp was 97.6and 1liter of fluids' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	01 Oct 2020 00:05:41
User closed query 'PV Query: Please confirm if hydrochlorothiazide was stopped in response to the event. Please leave query open until answer is available.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 18:37:36
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e CT head, ECG), and results of COVID testing if done. Please include units and reference ranges if applicable. Please leave query open until answer is available.' (Site from Safety).		25 Sep 2020 18:37:34
User closed query 'PV query: Please confirm if there were any treatments given to the subject (i.e. IV fluids). If so, please update the eCRF with the treatment medications. If not, please state so. Please leave query open until answer is available.' (Site from Safety).		25 Sep 2020 18:37:32
Query 'PV Query: Please confirm if hydrochlorothiazide was stopped in response to the event. Please leave query open until answer is available.' answered with 'patient did not specify' (Site from Safety).	maggie Tono (b) (4) (b) (4)	24 Sep 2020 17:01:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e CT head, ECG), and results of COVID testing if done. Please include units and reference ranges if applicable. Please leave query open until answer is available.' answered with 'patient did not disclose' (Site from Safety).	maggie Tono (b) (4)	24 Sep 2020 17:01:29
Query 'PV query: Please confirm if there were any treatments given to the subject (i.e. IV fluids). If so, please update the eCRF with the treatment medications. If not, please state so. Please leave query open until answer is available.' answered with 'patient did not disclose' (Site from Safety).	maggie Tono (b) (4)	24 Sep 2020 17:01:04
User opened query 'PV Query: Please confirm if hydrochlorothiazide was stopped in response to the event. Please leave query open until answer is available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 16:41:20
User closed query 'PV Query: Please confirm if hydrochlorothiazide was stopped in response to the event.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 16:41:20
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e CT head, ECG), and results of COVID testing if done. Please include units and reference ranges if applicable. Please leave query open until answer is available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 16:40:44
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e CT head, ECG), and results of COVID testing if done. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 16:40:44
User opened query 'PV query: Please confirm if there were any treatments given to the subject (i.e. IV fluids). If so, please update the eCRF with the treatment medications. If not, please state so. Please leave query open until answer is available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 16:39:54
User closed query 'PV query: Please confirm if there were any treatments given to the subject (i.e. IV fluids). If so, please update the eCRF with the treatment medications. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 16:39:54

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if hydrochlorothiazide was stopped in response to the event.' answered with 'will update ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	16 Sep 2020 16:59:43
Query 'PV query: Please confirm if there were any treatments given to the subject (i.e. IV fluids). If so, please update the eCRF with the treatment medications. If not, please state so.' answered with 'awaiting records from hospital, info is unknown at this time ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	16 Sep 2020 16:59:24
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e CT head, ECG), and results of COVID testing if done. Please include units and reference ranges if applicable.' answered with 'awaiting more information from hospital ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	16 Sep 2020 16:58:36
User opened query 'PV Query: Please confirm if hydrochlorothiazide was stopped in response to the event.' (Site from Safety).	(b) (4), (b) (6)	09 Sep 2020 14:20:37
User opened query 'PV query: Please confirm if there were any treatments given to the subject (i.e. IV fluids). If so, please update the eCRF with the treatment medications. If not, please state so.' (Site from Safety).		09 Sep 2020 14:19:32
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e CT head, ECG), and results of COVID testing if done. Please include units and reference ranges if applicable.' (Site from Safety).		09 Sep 2020 14:19:15
Query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from CRA).		06 Sep 2020 18:19:17
User opened query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).		01 Sep 2020 18:05:59

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient was golfing in 100 degree temperature and became dizzy followed by brief LOC. Taken to hospital and admitted for dehydration and hypotension. Lisinopril 40mg QD taken since 2012 was decreased to 20mg QD. Hospital records requested and pending at time of report. Pt was discharged home w/o sequelae on 17Aug2020.'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:44:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:44:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Dec 2020 20:23:48
User entered '0'	System	10 Nov 2020 21:49:56
User entered '1'	System	31 Aug 2020 01:44:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Aug 2020 01:44:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:25:29
Reviewed for Safety.		09 Sep 2020 17:49:58
User entered 'USA-US097-2020-mRNA-1273-P301000001'		09 Sep 2020 17:49:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:25:31
User coded data point as SOC: Vascular disorders, HLT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 19:39:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 19:39:46
Data point term sent to Coder	System	07 Sep 2020 19:38:31
User entered 'HYPOTENSION'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 19:30:06
User closed query 'Per source field is not completed (no data is specified) for medically-attended AE. Please reconcile. Thanks ' (Site from CRA).		23 Nov 2020 19:30:04
Query 'Per source field is not completed (no data is specified) for medically-attended AE. Please reconcile. Thanks ' answered with 'source has been updated to reflect eCRF' (Site from CRA).	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:12:26
User opened query 'Per source field is not completed (no data is specified) for medically-attended AE. Please reconcile. Thanks ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:25:25
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:43:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Sep 2020 19:43:21
User entered 'Yes (Y)' reason for change: Data Entry Error	maggie Tono (b) (4)	07 Sep 2020 19:43:21
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:38:18
User entered empty.	maggie Tono (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:25:33
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:25:35
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:25:36
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).		11 Sep 2020 16:13:49
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	07 Sep 2020 19:38:18
User entered '16 Aug 2020'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:25:38
User entered empty.	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:25:39
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:25:41
User entered '17 Aug 2020'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:25:43
User entered empty.	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

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Severity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 19:31:29
User closed query 'Severity is not specified. Please confirm an investigator completes the severity assessment and documents it in the source. Thank you' (Site from CRA).		23 Nov 2020 19:31:27
User closed query 'PV Query: Please confirm severity as grade 2/moderate for event of hypotension and dehydration as events caused hospitalization. Please consider updating severity to grade 4 for both events.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:04:35
Query 'Severity is not specified. Please confirm an investigator completes the severity assessment and documents it in the source. Thank you' answered with 'source and eCRF updated ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:14:05
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:12:57
Query 'PV Query: Please confirm severity as grade 2/moderate for event of hypotension and dehydration as events caused hospitalization. Please consider updating severity to grade 4 for both events.' answered with 'updated ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:12:41
User opened query 'Severity is not specified. Please confirm an investigator completes the severity assessment and documents it in the source. Thank you' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:27:12
User opened query 'PV Query: Please confirm severity as grade 2/moderate for event of hypotension and dehydration as events caused hospitalization. Please consider updating severity to grade 4 for both events.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:59:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	maggie Tono (b) (4)	07 Sep 2020 19:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:26:02
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	07 Sep 2020 19:44:43
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	07 Sep 2020 19:38:18
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:26:05
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:26:06
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:26:08
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	07 Sep 2020 19:44:43
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	07 Sep 2020 19:44:43
User entered '1' reason for change: Data Entry Error	maggie Tono (b) (4)	07 Sep 2020 19:44:43
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	07 Sep 2020 19:38:18
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

US3192006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:26:09
User entered '16 Aug 2020' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:43:21
User entered empty.	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

US3192006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:26:12
User entered '17 Aug 2020' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:44:06
User entered empty.	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

US3192006

Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:26:16
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

US3192006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:26:18
User entered empty.	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

US3192006

Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:28:55
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

US3192006

Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:28:57
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

US3192006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:28:59
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

US3192006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:02
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:44:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Sep 2020 19:44:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:44:06
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:38:18
User entered empty.	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
Query 'Per source this field is not document in source. Please reconcile. Thanks' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:40:16
DataPoint Verified.		21 Jan 2021 16:40:13
User opened query 'Per source this field is not document in source. Please reconcile. Thanks' (Site from CRA).		23 Nov 2020 19:32:15
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:44:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Sep 2020 19:44:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:44:06
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:38:18
User entered empty.	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:04
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:45:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Sep 2020 19:45:47
User entered 'None (NONE)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:45:47
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:38:18
User entered empty.	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

None

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:48
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Sep 2020 19:44:06
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Sep 2020 19:38:18
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

US3192006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
User closed query 'Per DM CLR: RQ: Response noted, however, no updates were provided. Please review response and record the treatment in their respective eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:10:55
Query 'Per DM CLR: RQ: Response noted, however, no updates were provided. Please review response and record the treatment in their respective eCRF as appropriate. Otherwise, clarify.' answered with 'this has been updated, con meds added as appropriate' (Site from DM).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:15:21
User opened query 'Per DM CLR: RQ: Response noted, however, no updates were provided. Please review response and record the treatment in their respective eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:44:41
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:29:50
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		06 Oct 2020 02:31:25
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Sep 2020 17:12:00
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:39:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	maggie Tono (b) (4)	07 Sep 2020 19:44:06
User entered '0'	(b) (4) maggie Tono (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:52
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:53
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:44:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Sep 2020 19:44:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:44:06
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:38:18
User entered empty.	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:55
User entered empty.	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
User closed query 'PV Query: Please confirm subject's BP of 71 at discharge from hospital. Was 71 systolic or diastolic? If diastolic, please provide systolic and diastolic reading.' (Site from Safety).	(b) (4)	22 Jan 2021 13:47:39
Query 'PV Query: Please confirm subject's BP of 71 at discharge from hospital. Was 71 systolic or diastolic? If diastolic, please provide systolic and diastolic reading.' answered with 'Discharge BP 141/64' (Site from Safety).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:34:40
User opened query 'PV Query: Please confirm subject's BP of 71 at discharge from hospital. Was 71 systolic or diastolic? If diastolic, please provide systolic and diastolic reading.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:17:48
User closed query 'PV Query: Please confirm subject's BP of 71 at discharge from hospital. Was 71 systolic or diastolic? If diastolic, please provide systolic and diastolic reading.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:04:48
Query 'PV Query: Please confirm subject's BP of 71 at discharge from hospital. Was 71 systolic or diastolic? If diastolic, please provide systolic and diastolic reading.' answered with 'unknown, awaiting medical records ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	21 Nov 2020 00:15:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:30:02
User opened query 'PV Query: Please confirm subject's BP of 71 at discharge from hospital. Was 71 systolic or diastolic? If diastolic, please provide systolic and diastolic reading.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:59:51
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e CT head, ECG), and results of COVID testing if done. Please include units and reference ranges if applicable. Please leave query open until answer is available.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 17:09:17
User closed query 'PV Query: Please provide the subject's blood pressure reading on admission and at discharge.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 17:09:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please confirm if there were any treatments given to the subject (i.e. IV fluids). If so, please update the eCRF with the treatment medications. If not, please state so. Please leave query open until answer is available.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 17:09:13
Query 'PV query: Please confirm if there were any treatments given to the subject (i.e. IV fluids). If so, please update the eCRF with the treatment medications. If not, please state so. Please leave query open until answer is available.' answered with 'yes he did receive an iv 100cc/h its noted in the medical records from the hospital ' (Site from Safety).	maggie Tono (b) (4)	09 Oct 2020 19:41:32
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e CT head, ECG), and results of COVID testing if done. Please include units and reference ranges if applicable. Please leave query open until answer is available.' answered with 'covid test was negative, and no ct head was not done ' (Site from Safety).	maggie Tono (b) (4)	09 Oct 2020 19:38:51
Query 'PV Query: Please provide the subject's blood pressure reading on admission and at discharge.' answered with 'blood pressure was 90 when patient 1st arrived and then after 71 when he was discharged' (Site from Safety).	maggie Tono (b) (4)	09 Oct 2020 19:27:30
User opened query 'PV query: Please confirm if there were any treatments given to the subject (i.e. IV fluids). If so, please update the eCRF with the treatment medications. If not, please state so. Please leave query open until answer is available.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:10:23
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e CT head, ECG), and results of COVID testing if done. Please include units and reference ranges if applicable. Please leave query open until answer is available.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:10:07
User opened query 'PV Query: Please provide the subject's blood pressure reading on admission and at discharge.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:09:51

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if hydrochlorothiazide was stopped in response to the event.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:01:55
User closed query 'PV query: Please confirm if there were any treatments given to the subject (i.e. IV fluids). If so, please update the eCRF with the treatment medications. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:01:52
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e CT head, ECG), and results of COVID testing if done. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:01:47
User closed query 'PV Query: Please provide the subject's blood pressure reading on admission and at discharge.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:01:44
Query 'PV Query: Please confirm if hydrochlorothiazide was stopped in response to the event.' answered with 'yes, med stopped' (Site from Safety).	Yvonne De Los Reyes (b) (4)	26 Sep 2020 21:06:26
Query 'PV query: Please confirm if there were any treatments given to the subject (i.e. IV fluids). If so, please update the eCRF with the treatment medications. If not, please state so.' answered with 'Unknown, awaiting hospital discharge summary' (Site from Safety).	Yvonne De Los Reyes (b) (4)	26 Sep 2020 21:04:31
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e CT head, ECG), and results of COVID testing if done. Please include units and reference ranges if applicable.' answered with 'awaiting hospital summary' (Site from Safety).	Yvonne De Los Reyes (b) (4)	26 Sep 2020 21:02:53
Query 'PV Query: Please provide the subject's blood pressure reading on admission and at discharge.' answered with 'awaiting hospital summary' (Site from Safety).	Yvonne De Los Reyes (b) (4)	26 Sep 2020 21:02:36
User opened query 'PV Query: Please confirm if hydrochlorothiazide was stopped in response to the event.' (Site from Safety).	(b) (4), (b) (6)	09 Sep 2020 14:20:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please confirm if there were any treatments given to the subject (i.e. IV fluids). If so, please update the eCRF with the treatment medications. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Sep 2020 14:19:56
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e CT head, ECG), and results of COVID testing if done. Please include units and reference ranges if applicable.' (Site from Safety).		09 Sep 2020 14:18:49
User opened query 'PV Query: Please provide the subject's blood pressure reading on admission and at discharge.' (Site from Safety).		09 Sep 2020 14:18:31
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	07 Sep 2020 19:45:47
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	07 Sep 2020 19:45:47
User entered 'PATIENT WAS GOLFING IN 100 DEGREE TEMPERATURE AND BECAME DIZZY FOLLOWED BY BRIEF LOC. TAKEN TO HOSPITAL AND ADMITTED FOR DEHYDRATION AND HYPOTENSION. LISINOPRIL 40MG QD TAKEN SINCE 2012 WAS DECREASED TO 20MG QD. HOSPITAL RECORDS REQUESTED AND PENDING AT TIME OF REPORT. PT WAS DISCHARGED HOME W/O SEQUELAE ON 17AUG2020.' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:45:47
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	07 Sep 2020 19:38:18
User entered empty.	maggie Tono (b) (4) (b) (4)	07 Sep 2020 19:38:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 19:38:18

US3192006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 19:43:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Sep 2020 19:38:18

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (u) (*), (b) (6)	21 Jan 2021 16:40:24
Reviewed for Safety.		21 Jan 2021 15:54:23
User entered 'USA-US097-2020-mRNA-1273-P301000001'		21 Jan 2021 15:54:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:09:23
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:53:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:53:50
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:27:39
Data point term sent to Coder	System	16 Mar 2021 00:26:16
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	16 Mar 2021 00:25:58
User entered 'WORSENING chronic kidney disease' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	16 Mar 2021 00:25:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:22:05
Data point term sent to Coder	System	15 Mar 2021 15:41:46
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	15 Mar 2021 15:41:07
Coding entries removed.	Yvonne De Los Reyes (b) (4)	15 Mar 2021 15:41:07
User entered 'worsening ACUTE RENAL FAILURE' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	15 Mar 2021 15:41:07
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	15 Mar 2021 15:40:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 02:13:10
	(b) (4), (b) (6)	21 Jan 2021 16:40:28
User coded data point as SOC: Renal and urinary disorders, HLG: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute renal failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 01:28:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 01:28:18
Data point term sent to Coder	System	21 Jan 2021 01:27:46
User entered 'Acute Renal Failure'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:46:41
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:46:45
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:46:52
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:46:55
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:46:57
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:01
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:02
User entered '17 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:04
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:08
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	21 Jan 2021 01:28:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:28:09
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	21 Jan 2021 01:27:55
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:13
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:15
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:16
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	21 Jan 2021 01:27:55
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	21 Jan 2021 01:27:55
User entered '1' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:55
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	21 Jan 2021 01:27:45
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:18
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:19
User entered '17 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:21
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:23
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:25
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:27
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:31
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:33
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:47:38
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:48:03
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, please confirm what has been updated as there is still NO CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:54:58
Query 'Per DM CLR - RQ: Site's response noted. However, please confirm what has been updated as there is still NO CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'no treatment given with fluids ' (Site from DM).	maggie Tono (b) (4) (b) (4)	06 Apr 2021 23:55:23
User opened query 'Per DM CLR - RQ: Site's response noted. However, please confirm what has been updated as there is still NO CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 03:26:26
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:09:32
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:27:51

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

None

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	15 Mar 2021 15:41:26
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Mar 2021 15:41:07
User entered '1' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	15 Mar 2021 15:41:07
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Mar 2021 23:45:20
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 23:45:20
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 23:45:20
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:35:49
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:48:08
User entered '1'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:48:37
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:48:39
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:48:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:48:47
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:48:53
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Jan 2021 01:29:04
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	21 Jan 2021 01:29:04
User entered 'while in hospital patient developed acute renal failure due to dehydration.' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:29:04
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Jan 2021 01:28:09
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 01:28:09
User entered '0'	System	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:39:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 01:27:45

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:48:59
Reviewed for Safety.		21 Jan 2021 15:55:26
User entered 'USA-US097-2020-mRNA-1273-P301000001'		21 Jan 2021 15:54:47

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:49:00
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hyperkalemia, LLT: Hyperkalemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 01:33:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 01:33:11
Data point term sent to Coder	System	21 Jan 2021 01:32:47
User entered 'Hyperkalemia'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:49:02
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:49:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:49:21
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:49:24
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:49:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:49:45
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:49:51
User entered '17 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:49:52
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:49:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:02
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Jan 2021 01:37:24
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Jan 2021 01:32:46
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:04
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:06
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:09
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	21 Jan 2021 01:37:24
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	21 Jan 2021 01:37:24
User entered '1' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:37:24
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	21 Jan 2021 01:32:46
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:15
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:16
User entered '17 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:20
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:22
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:24
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:25
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:28
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:30
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:33
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:35
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:36
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:38
User entered 'I'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:40
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:50:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:51:03
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:51:10
User entered 'Due to dehydration, patient was diagnosed with hyperkalemia while in hospital.'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Jan 2021 01:32:46

US3192006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:39:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 01:32:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:12:49
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Query 'Please review source and confirm if 'lovastatin', 'lactated ringers', 'glucagon', 'glucose', and 'ondansetron' should be added as con. meds. Thanks' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:12:44
User opened query 'Please review source and confirm if 'lovastatin', 'lactated ringers', 'glucagon', 'glucose', and 'ondansetron' should be added as con. meds. Thanks' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 17:11:14
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:24:23
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	02 Aug 2020 01:31:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:22:52
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 CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 01:47:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 01:47:40
Data point term sent to Coder	System	31 Aug 2020 01:46:49
User entered 'Testosterone Cypionate'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered 'Low Testosterone'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered '100'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered 'every week (QS)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered 'Intramuscular (INTRAMUSCULAR)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered 'un UNK 2015'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:52
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	31 Aug 2020 01:46:37

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Nov 2020 17:27:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 17:27:22
Data point term sent to Coder	System	03 Nov 2020 17:26:58
Coding entries removed.	Yvonne De Los Reyes (b) (4)	03 Nov 2020 17:26:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 00:53:06
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 Oct 2020 00:53:06
Data point term sent to Coder	System	31 Oct 2020 00:52:36
Coding entries removed.	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:51:35
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:20:27

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 01:48:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 01:48:43
Data point term sent to Coder	System	31 Aug 2020 01:47:49
User entered 'Aspirin'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:41
User closed query 'Please confirm if Aspirin is being used as a prophylaxis (ie, preventative measure). Thanks' (Site from CRA).		12 Nov 2020 19:35:37
Query 'Please confirm if Aspirin is being used as a prophylaxis (ie, preventative measure). Thanks' answered with 'aspirin is not a prophylaxis' (Site from CRA).	maggie Tono (b) (4) (b) (4)	11 Nov 2020 18:40:28
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	11 Nov 2020 18:40:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:51:35
User opened query 'Please confirm if Aspirin is being used as a prophylaxis (ie, preventative measure). Thanks' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:18:33
User entered 'No (N)' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	30 Sep 2020 17:09:49
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:42
User closed query 'Per completion guidelines if medication is preventative/prophylaxis it recommends entry of indication to be "prophylaxis for ..."' (Site from CRA).		12 Nov 2020 19:35:39
Query 'Per completion guidelines if medication is preventative/prophylaxis it recommends entry of indication to be "prophylaxis for ..."' answered with 'preventative' (Site from CRA).	maggie Tono (b) (4) (b) (4)	11 Nov 2020 18:39:25
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:26:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:26:46
User entered 'preventative' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Nov 2020 17:26:46
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Oct 2020 00:51:35
User entered empty; reason for change Data Entry Error	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:51:35
User opened query 'Per completion guidelines if medication is preventative/prophylaxis it recommends entry of indication to be "prophylaxis for ..."' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:20:14
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 14:11:31
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	30 Sep 2020 17:10:05
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 10:14:28

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EAB) (1725)

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US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Preventative'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:23
User entered '81'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:25
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:29
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:30
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:31
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:33
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:35
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:36
User entered 'un UNK 2012'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:38
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:39
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:40
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:42
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 01:47:16

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 01:49:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 01:49:44
Data point term sent to Coder	System	31 Aug 2020 01:48:50
User entered 'Hydrochlorothiazide'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered 'Hypertension'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered '25'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered 'un UNK 2015'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:55
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User entered '1'	System	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User entered '1'	System	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:55
User entered '804 (804)'	System	31 Aug 2020 01:48:12

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:22:58
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 01:50:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 01:50:44
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 01:49:51
User entered 'Levothyroxine'	Yvonne De Los Reyes	31 Aug 2020 01:48:55
	(b) (4)	

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered 'Hypothyroidism'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered '150'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered 'ug (ug)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered 'un UNK 2012'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:58
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 01:48:55

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 01:50:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 01:50:44
Data point term sent to Coder	System	31 Aug 2020 01:49:50
User entered 'Lisinopril'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:23
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:33
User entered 'Hypertension'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:34
Query 'Per SAE of dehydration and hypotension, subject's Lisinopril was reduced to 20 mg. Please update source and RAVE data as needed regarding Lisinopril use. Thank you' canceled (Site from CRA).		30 Oct 2020 18:16:19
User opened query 'Per SAE of dehydration and hypotension, subject's Lisinopril was reduced to 20 mg. Please update source and RAVE data as needed regarding Lisinopril use. Thank you' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:15:27
User entered '40'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:36
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:38
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:39
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:40
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:42
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:43
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:44
User entered 'un UNK 2012'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:46
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:49
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:35:48
DataPoint Un-verified.		30 Oct 2020 18:23:01
DataPoint Verified.		30 Oct 2020 18:16:51
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User entered '1'	System	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User entered '1'	System	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:53:58
User entered '804 (804)'	System	31 Aug 2020 01:49:43

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:23:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 01:51:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 01:51:46
Data point term sent to Coder	System	31 Aug 2020 01:50:52
User entered 'Metformin'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered 'Diabetes Mellitus II'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered '1000'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered 'twice daily (BID)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered 'un UNK 2015'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:02
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 01:50:21

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:23:04
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 01:52:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 01:52:38
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 01:51:52
User entered 'Fish Oil'	Yvonne De Los Reyes	31 Aug 2020 01:51:00
	(b) (4)	

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered 'preventative'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered '1000'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered 'un UNK 2016'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 01:51:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 01:52:38
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 01:52:38
Data point term sent to Coder	System	31 Aug 2020 01:51:52
User entered 'Vitamin D'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered 'Preventative'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered '1000'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered 'un UNK 2016'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:05
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 01:51:33

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:07:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:07:43
Data point term sent to Coder	System	31 Aug 2020 01:52:55
User entered 'Glucosamine'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered 'Preventative'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered '1500'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered 'un UNK 2015'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:07
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 01:52:08

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 05:26:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 05:26:38
Data point term sent to Coder	System	31 Aug 2020 01:52:56
User entered 'Chondroitin/Msm complex'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. ' (Site from DM).		01 Oct 2020 17:56:47
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. ' answered with 'entered according to patient ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	30 Sep 2020 17:16:24
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 10:14:43
User entered 'preventative'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered '1103'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered 'un UNK 2015'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:23:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 01:52:52

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:24:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 01:54:41
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 01:54:41
Data point term sent to Coder	System	31 Aug 2020 01:53:57
User entered 'Lisinopril'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered 'Hypertension'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered '20'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:05
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 01:53:25

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 16:55:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: LOVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 01:09:12
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	21 Jan 2021 01:09:12
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	21 Jan 2021 01:08:44
User entered 'Lovastatin'	Yvonne De Los Reyes	21 Jan 2021 01:08:44
	(b) (4)	

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:23
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:25
User entered 'Hyperlipidemia'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:26
User entered '20'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:28
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:29
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:31
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:33
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:34
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:36
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:22:24
User closed query 'Please confirm start date was day of hospital admission. Per medical records this might be part of the subject's historic medication list, so start date was prior to 16Aug2020. Thanks' (Site from CRA).		26 Jan 2021 18:22:13
Query 'Please confirm start date was day of hospital admission. Per medical records this might be part of the subject's historic medication list, so start date was prior to 16Aug2020. Thanks' answered with 'updated' (Site from CRA).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:32:55
User entered '14 Jul 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:32:46
User opened query 'Please confirm start date was day of hospital admission. Per medical records this might be part of the subject's historic medication list, so start date was prior to 16Aug2020. Thanks' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:55:11
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:15
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:17
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:18
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:55:20
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Jan 2021 01:08:44

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:39:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:39:57
Data point term sent to Coder	System	15 Mar 2021 15:38:43
Coding entries removed.	Yvonne De Los Reyes (b) (4)	15 Mar 2021 15:38:27
User signature succeeded.	John McGettigan (b) (4) (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:56:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 01:14:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 01:14:17
Data point term sent to Coder	System	21 Jan 2021 01:13:45
User entered 'Lactated Ringers'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:56:32
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 00:30:10
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		15 Mar 2021 23:07:52
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	15 Mar 2021 15:39:11
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	15 Mar 2021 15:38:27
Signature has been broken.	Yvonne De Los Reyes (b) (4)	15 Mar 2021 15:38:27
User entered 'dehydration' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	15 Mar 2021 15:38:27
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:52:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:56:33
User entered 'Electrolyte Replenishment'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:56:47
Query 'Per source dose is 1000. Please reconcile. Thanks' canceled (Site from CRA).		21 Jan 2021 16:56:45
User opened query 'Per source dose is 1000. Please reconcile. Thanks' (Site from CRA).		21 Jan 2021 16:56:25
User entered '100'		21 Jan 2021 01:13:07
	Yvonne De Los Reyes (b) (4)	

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:56:35
User entered 'mL (mL)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:56:53
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:56:51
User entered 'other (OTHER)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:56:49
User entered 'every hour'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:56:55
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:57:07
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:57:09
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:57:11
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:57:13
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:57:14
User entered '17 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:57:16
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User entered empty.	System	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User entered empty.	System	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:20
User entered empty.	System	21 Jan 2021 01:13:07

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PANCREATIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, PRODUCT: GLUCAGON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 00:29:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 00:29:19
Data point term sent to Coder	System	21 Jan 2021 18:16:39
Coding entries removed.	Yvonne De Los Reyes	21 Jan 2021 18:16:25
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:57:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PANCREATIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, PRODUCT: GLUCAGON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 07:40:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 07:40:20
Data point term sent to Coder	System	21 Jan 2021 02:10:58
User entered 'glucagon'	Yvonne De Los Reyes	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:23:26
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:16:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:16:25
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:57:41
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:23:28
User closed query 'Per source indication is 'hypoglycemia'. Please reconcile. Thanks' (Site from CRA).		21 Jan 2021 19:23:17
Query 'Per source indication is 'hypoglycemia'. Please reconcile. Thanks' answered with 'reconciled' (Site from CRA).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:16:32
User entered 'prophylaxis for hypoglycemia' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:16:25
User opened query 'Per source indication is 'hypoglycemia'. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 17:02:39
User entered 'Electrolyte Replenishment'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:02:43
User entered '100'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:02:44
User entered 'mL (mL)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:02:46
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:02:47
User entered 'other (OTHER)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:02:49
User entered 'per hour'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:02:50
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:02:52
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:02:53
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:02:55
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:02:57
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:02:58
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:00
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User entered empty.	System	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User entered empty.	System	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:21
User entered empty.	System	21 Jan 2021 02:09:57

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:04
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: CARBOHYDRATES, PRODUCT: GLUCOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 14:43:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 14:43:08
Data point term sent to Coder	System	21 Jan 2021 02:10:57
User entered 'Glucose Infusion'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:06
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:07
User entered 'Hyperkalemia'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:10
User entered '12.5' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:30
User entered '1'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:12
User entered 'g (g)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:30
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:13
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:17
User entered 'as needed (PRN)' reason for change:	Yvonne De Los Reyes	21 Jan 2021 02:14:30
Data Entry Error	(b) (4)	
User entered 'once (ONCE)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:20
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:39
DataPoint Un-verified.		21 Jan 2021 17:03:25
DataPoint Verified.		21 Jan 2021 17:03:23
User entered 'Intramuscular (INTRAMUSCULAR)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:41
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:42
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:44
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:45
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:47
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:03:49
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User entered empty.	System	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User entered empty.	System	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:23
User entered empty.	System	21 Jan 2021 02:10:46

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 05:44:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 05:44:14
Data point term sent to Coder	System	21 Jan 2021 18:21:44
Coding entries removed.	Yvonne De Los Reyes	21 Jan 2021 18:21:17
DataPoint Verified.	(b) (4)	21 Jan 2021 17:03:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 07:42:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 07:42:16
Data point term sent to Coder	System	21 Jan 2021 02:14:01
User entered 'Ondansetron'	Yvonne De Los Reyes	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:23:45
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:21:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:21:17
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:03:55
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:23:47
User closed query 'Is nausea/vomiting symptoms of another event or is Ondansetron given to prevent these symptoms from occurring?' (Site from CRA).		21 Jan 2021 19:23:44
Query 'Is nausea/vomiting symptoms of another event or is Ondansetron given to prevent these symptoms from occurring?' answered with 'updated ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:21:23
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:21:17
User entered 'prophylactic for NAUSEA/VOMITING' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:21:17
User opened query 'Is nausea/vomiting symptoms of another event or is Ondansetron given to prevent these symptoms from occurring?' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 17:06:51
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:06:03
User entered 'nausea/vomiting'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:06:04
User entered '4'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:06:55
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:06:59
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:07:02
User entered 'as needed (PRN)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:07:04
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:07:06
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:07:08
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:07:10
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:07:13
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:07:15
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:07:17
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:07:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User entered empty.	System	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User entered empty.	System	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:54:27
User entered empty.	System	21 Jan 2021 02:14:00

US3192006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:39:06

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:24:19
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	02 Sep 2020 03:09:15

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:20
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:26
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:28
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:30
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:00:45
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:31
Reviewed for Safety.		28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:20
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 19:25:26
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:30
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:00:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:31
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:39:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '31/Aug/2020 11:04'	(b) (4) System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:39:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'I'		31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:20
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:26
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:28
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:30
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:00:45
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:31
Reviewed for Safety.		28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:39:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '09/Sep/2020 13:51'	(b) (4) System	09 Sep 2020 17:51:40

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:39:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	25 Sep 2020 18:38:07
User entered 'I'		09 Sep 2020 17:51:40

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 18:59:20
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:26
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:28
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:30
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:00:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:31
Reviewed for Safety.		28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:39:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '25/Sep/2020 14:38'	(b) (4) System	25 Sep 2020 18:38:20

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:39:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:02:07
User entered 'I'		25 Sep 2020 18:38:20

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 18:59:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:28
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:30
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:00:45
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:31
Reviewed for Safety.		28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:39:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '28/Sep/2020 15:02'	(b) (4) System	28 Sep 2020 15:02:34

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:39:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:09:34
User entered 'I'		28 Sep 2020 15:02:34

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:20
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:26
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:28
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:00:45
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:31
Reviewed for Safety.		28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:39:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '12/Oct/2020 13:09'	(b) (4) System	12 Oct 2020 17:09:46

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:39:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:10:02
User entered 'I'		12 Oct 2020 17:09:46

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:20
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:30
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:00:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:31
Reviewed for Safety.		28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:39:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '11/Nov/2020 19:26'	(b) (4) System	12 Nov 2020 00:26:34

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:39:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:05:02
User entered 'I'		12 Nov 2020 00:26:34

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:20
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:26
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:00:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:31
Reviewed for Safety.		28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:39:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '23/Nov/2020 15:05'	(b) (4) System	23 Nov 2020 15:05:27

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:39:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 20:48:36
User entered 'I'		23 Nov 2020 15:05:27

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:20
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:26
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:30
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:00:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:31
Reviewed for Safety.		28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:39:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '08/Dec/2020 20:48'	(b) (4) System	08 Dec 2020 20:48:48

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:39:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 21:38:26
User entered 'I'		08 Dec 2020 20:48:48

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:20
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:26
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:28
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:30
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:00:45
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:31
Reviewed for Safety.		28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:39:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '07/Jan/2021 16:38'	(b) (4) System	07 Jan 2021 21:38:42

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:39:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:56:37
User entered 'I'		07 Jan 2021 21:38:42

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:20
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:28
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:30
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:00:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:31
Reviewed for Safety.		28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:39:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered '21/Jan/2021 15:57'	(b) (4) System	21 Jan 2021 15:57:07

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:39:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 00:31:08
Reviewed for Safety.		03 Mar 2021 15:39:05
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:57:07

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:20
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4)	12 Nov 2020 19:25:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:30
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:00:45
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:31
Reviewed for Safety.		28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 15:39:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 00:31:08
User entered '03/Mar/2021 10:39'	System	03 Mar 2021 15:39:23

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 15:39:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:07:16
DataPoint Verified.		16 Mar 2021 00:31:08
User entered 'I'		03 Mar 2021 15:39:23

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:45
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'USA-US097-2020-MRNA-1273-P301000001'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:43
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:46
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:58:48
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:11
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'Yes (Y)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:13
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:15
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:16
Reviewed for Safety.		31 Aug 2020 15:04:42
User entered 'No (N)'	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:18
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'John'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:59:20
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'McGettigan'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:26
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '5390 E. Erickson Drive'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:28
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'Tucson'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:30
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered 'AZ'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:00:45
Reviewed for Safety.		25 Sep 2020 18:38:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:15
Amendment Manager: User entered '85712'	System	14 Sep 2020 21:42:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
Un-reviewed for Safety.	System	09 Sep 2020 17:49:40
User entered empty.	System	09 Sep 2020 17:49:40
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 15:04:42
User entered (b) (6)	System	31 Aug 2020 15:04:09

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:31
Reviewed for Safety.		28 Sep 2020 15:02:07
Un-reviewed for Safety.	System	25 Sep 2020 18:38:20
User entered 'US'	System	25 Sep 2020 18:38:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:38:07
Un-reviewed for Safety.	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	10 Sep 2020 14:51:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:51:23
User entered 'US' (non-conformant).	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	16 Mar 2021 16:08:13
User entered '11'	System	03 Mar 2021 15:39:23
User signature succeeded.	John McGettigan (b) (4)	20 Feb 2021 19:35:15
	(b) (4)	
User entered '10'	System	21 Jan 2021 15:57:07
User entered '9'	System	07 Jan 2021 21:38:42
User entered '8'	System	08 Dec 2020 20:48:48
User entered '7'	System	23 Nov 2020 15:05:27
User entered '6'	System	12 Nov 2020 00:26:34
User entered '5'	System	12 Oct 2020 17:09:46
User entered '4'	System	28 Sep 2020 15:02:34
User entered '3'	System	25 Sep 2020 18:38:20
User entered '2'	System	09 Sep 2020 17:51:40
User entered '1'	System	31 Aug 2020 15:04:50

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 15:39:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:50:31
User entered '16/Mar/2021 11:08'	System	16 Mar 2021 16:08:13

US3192006

Folder: SAE USA-US097-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 15:39:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 13:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:50:31
User entered 'I'		16 Mar 2021 16:08:13