

US3122010 (Prod: M3 Wake Research, Inc - M3 Wake)

Generated By: (b) (6)

Generated On: 11 Jun 2021 14:57:14

All time stamps listed in this document are displayed in GMT

US3122010

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:09:40

Generated On: 11 Jun 2021 14:57:14

[Participant ID](#)

US3122010

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

US3122010

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 JUL 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

US3122010

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
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

US3122010

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

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

Month and Year of Informed Consent (derived) JUL 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

US3122010

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3122010

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Mar 2021 17:18:56

Generated On: 11 Jun 2021 14:57:14

Condition	SEVERE DRY MOUTH
Start date (dd MMM yyyy)	UN APR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3122010

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Mar 2021 17:18:56

Generated On: 11 Jun 2021 14:57:14

Condition	THROAT CANCER
Start date (dd MMM yyyy)	UN FEB 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

US3122010

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Mar 2021 17:18:56

Generated On: 11 Jun 2021 14:57:14

Condition	PULMONARY EMBOLISM
Start date (dd MMM yyyy)	30 MAY 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	30 MAY 2019
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2019
Start Year (derived)	2019
Stop Month and Year (derived)	MAY 2019
Stop Year (derived)	2019

US3122010

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Mar 2021 17:18:56

Generated On: 11 Jun 2021 14:57:14

Condition	SHINGLES VACCINE - FLU SYMPTOMS
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3122010

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Mar 2021 17:18:56

Generated On: 11 Jun 2021 14:57:14

Condition	ALLERGY TO HYDROCHLOROTHIAZIDE - HIVES
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3122010

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Mar 2021 17:18:56

Generated On: 11 Jun 2021 14:57:14

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Mar 2021 17:18:56

Generated On: 11 Jun 2021 14:57:14

Condition	THYROID NODULES - BENIGN
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Mar 2021 17:18:56

Generated On: 11 Jun 2021 14:57:14

Condition	RADIATION THERAPY (FOR THROAT CANCER)
Start date (dd MMM yyyy)	UN MAR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

US3122010

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Mar 2021 17:18:56

Generated On: 11 Jun 2021 14:57:14

Condition	CHEMOTHERAPY (FOR THROAT CANCER)
Start date (dd MMM yyyy)	UN MAR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

US3122010

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Mar 2021 17:18:56

Generated On: 11 Jun 2021 14:57:14

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Mar 2021 17:18:56

Generated On: 11 Jun 2021 14:57:14

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

US3122010

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	10:40 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 10:40
Height (<i>xxx.x</i>)	71 in
Weight (<i>xxx.x</i>)	182 lb
BMI (<i>xxx.x</i>)	25.43692 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) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JUL 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) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

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 RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 JUL 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

US3122010

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

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

What was the participant's randomization number? 142026

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 ☒

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JUL 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 10:40
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JUL 2020
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 12:35
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3122010

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

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.

US3122010

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:03 (24 HR)

Treatment Date and Time (derived) 27 JUL 2020 12:03

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JUL 2020

Collection time (00:00-23:59)

11:29 (24 HR)

Collection date and time (derived)

27 JUL 2020 11:29

US3122010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Collection date (dd MMM yyyy)			27 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:32	27 JUL 2020 11:32
Nasopharyngeal Swab 2	No		

US3122010

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

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

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

27 JUL 2020 12:23

PC Close Date & Time

27 JUL 2020 14:53

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 27 JUL 2020 15:48

PC Close Date & Time 28 JUL 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

28 JUL 2020 19:24

PC Open Date & Time

28 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 JUL 2020 18:47

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:57:14

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

97.4 °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

30 JUL 2020 13:32

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

31 JUL 2020 15:41

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:57:14

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 12:08

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 21:13

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

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 ☐

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.**

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

PC Open Date & Time

27 JUL 2020 12:23

PC Close Date & Time

27 JUL 2020 14:53

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

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 ☐

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.**

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

PC Open Date & Time

27 JUL 2020 15:48

PC Close Date & Time

28 JUL 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 JUL 2020 19:25

PC Open Date & Time

28 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

50

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 - **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 JUL 2020 18:46

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 13:27

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 15:42

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 12:09

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 21:14

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

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 ☐

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

27 JUL 2020 12:23

PC Close Date & Time

27 JUL 2020 14:53

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

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 ☐

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

27 JUL 2020 15:48

PC Close Date & Time

28 JUL 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

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 ☒

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

Yes <input type="checkbox"/>	
PC Time stamp	28 JUL 2020 19:26
PC Open Date & Time	28 JUL 2020 12:00
PC Close Date & Time	29 JUL 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

Yes <input type="checkbox"/>	
PC Time stamp	29 JUL 2020 18:48
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

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

56 of 1444

EAB) (1725)

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 13:28
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

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 ☒

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 15:42
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

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

60 of 1444

EAB) (1725)

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 12:10
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 1444

EAB) (1725)

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 21:14
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 03 AUG 2020 12:02

PC Open Date & Time 03 AUG 2020 12:00

PC Close Date & Time 04 AUG 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp 04 AUG 2020 21:13

PC Open Date & Time 04 AUG 2020 12:00

PC Close Date & Time 05 AUG 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 AUG 2020 12:02
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3122010

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 AUG 2020 21:13
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3122010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122010

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:09:40

Generated On: 11 Jun 2021 14:57:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122010

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:09:40

Generated On: 11 Jun 2021 14:57:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:09:40

Generated On: 11 Jun 2021 14:57:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122010

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:09:40

Generated On: 11 Jun 2021 14:57:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

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

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:30
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3122010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

US3122010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3122010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 AUG 2020

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

25 AUG 2020 10:15

US3122010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:25	25 AUG 2020 10:25
Nasopharyngeal Swab 2	No		

US3122010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:09:40

Generated On: 11 Jun 2021 14:57:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122010

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:09:40

Generated On: 11 Jun 2021 14:57:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 20:47:49

Generated On: 11 Jun 2021 14:57:14

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

RECURRENCE OF THROAT
CANCER & PCP REQUESTING
UNBLINDING LEAD TO SAFETY
CALL NOT BEING PERFORMED
DUE TO SITE WAITING FOR
GUIDANCE ON THE
EMERGENCY UNBLINDING.
GUIDANCE CAME AFTER
UPPER LIMIT WINDOW.

US3122010

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:09:40

Generated On: 11 Jun 2021 14:57:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:05:23

Generated On: 11 Jun 2021 14:57:14

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

US3122010

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:09:40

Generated On: 11 Jun 2021 14:57:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3122010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

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.

US3122010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

10:49 (24 HR)

Collection date and time (derived)

21 SEP 2020 10:49

US3122010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:09:41

Generated On: 11 Jun 2021 14:57:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 SEP 2020 00:02:24
Patient Cloud Open Date & Time	26 SEP 2020 00:01
Patient Cloud Close Date & Time	30 SEP 2020 23:59

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

07 OCT 2020 12:40:55

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

13 OCT 2020 19:04:43

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

26 OCT 2020 12:02:30

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 10:29:41
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

07 NOV 2020 18:43:03

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 17:35:42

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

25 NOV 2020 12:53:16

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 00:02:18

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 08:20:13

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 00:01:36

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 07:48:28

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 07:45:14

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	06 JAN 2021 14:05:59
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 00:02:43

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 08:23:59

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

27 JAN 2021 00:05:42

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 12:01:24
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 00:01:36
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 13:04:33

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

26 FEB 2021 17:00:30

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 18:26:26

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

12 MAR 2021 11:31:41

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3122010

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Jun 2021 14:57:14

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		03 MAR 2021 18:26:52

US3122010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 20:47:49

Generated On: 11 Jun 2021 14:57:14

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

US3122010

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 20:47:49

Generated On: 11 Jun 2021 14:57:14

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3122010

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Mar 2021 20:47:49

Generated On: 11 Jun 2021 14:57:14

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3122010

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

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 20:47:49

Generated On: 11 Jun 2021 14:57:14

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID UNBLND_DECIDE

US3122010

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

Form: Unblinding

Data signed: (b) (4) 15 Apr 2021 19:15:38

Generated On: 11 Jun 2021 14:57:14

Date of updated informed consent (<i>dd MMM yyyy</i>)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 SEP 2020
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	

US3122010

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 20:47:49

Generated On: 11 Jun 2021 14:57:14

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3122010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Mar 2021 20:47:49

Generated On: 11 Jun 2021 14:57:14

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3122010

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Mar 2021 18:54:42

Generated On: 11 Jun 2021 14:57:14

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 19:16:50

Generated On: 11 Jun 2021 14:57:14

AEID USA-US063-2020-MRNA-1273-P30
1000001

Adverse event RECURRENCE OF THROAT
CANCER [WITH METASTASES
TO LUNGS]

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

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

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

Start date (dd MMM yyyy) 12 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☒
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐
Grade 2/Moderate ☐
Grade 3/Severe ☒
Grade 4 ☐

Is the adverse event serious? Yes ☒
No ☐

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐

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EAB) (1725)

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US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 19:16:50

Generated On: 11 Jun 2021 14:57:14

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

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 19:16:50

Generated On: 11 Jun 2021 14:57:14

SUBJECT WITH A HISTORY OF THROAT CANCER WAS CALLED ON 18AUG2020 FOR SAFETY CALL #3. SUBJECT REPORTED THAT DURING A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED AND HAS SPREAD TO THEIR LUNGS. PATIENT IS SCHEDULED FOR ONCOLOGY FOLLOW-UP ON 02SEP2020. MORE DETAILS, INCLUDING TREATMENT/PROCEDURES WILL BE REPORTED AS THE DATA BECOMES AVAILABLE. 9/24/2020 VISIT INFORMATION (ADDED FROM MEDICAL RECORDS RECEIVED 09OCT2020) DIAGNOSIS: SUBJECT IS DIAGNOSED WITH SQUAMOUS CELL CARCINOMA - LEFT TONSIL. STAGE: T2N2 (AJCC 8TH EDITION) T2N2C (7TH EDITION) MOLECULAR: P16+ GENE VARIANCE OF UNCERTAIN SIGNIFICANCE: CTNNB1: C.97T>A [P.SER33THR] CPS 2 ON CYCLE 1 OF PEMBROLIZUMAB. PLAN(DOCTOR'S NOTES): #SCC - LEFT TONSIL, T2N2 -NOW WITH BIOPSY PROVEN RECURRENT/METASTATIC DISEASE IN THE LUNGS -GIVEN LOW BURDEN, ASYMPTOMATIC DISEASE AND PD-L1 CPS 2, WILL PROCEED WITH FRONT LINE PEMBROLIZUMAB PER KN048. [CYCLE ONE STARTED SAME DAY AS NOTES]

Serious Adverse Event Derived (CSA Programming Field Only)	1
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Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

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US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 19:16:50

Generated On: 11 Jun 2021 14:57:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 19:16:50

Generated On: 11 Jun 2021 14:57:14

AEID USA-US063-2020-MRNA-1273-P30
1000001

Adverse event METASTASES TO LUNGS
[RECURRENCE OF THROAT
CANCE]

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

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

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

Start date (dd MMM yyyy) 12 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☒
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐
Grade 2/Moderate ☐
Grade 3/Severe ☒
Grade 4 ☐

Is the adverse event serious? Yes ☒
No ☐

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐

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EAB) (1725)

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US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 19:16:50

Generated On: 11 Jun 2021 14:57:14

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

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 19:16:50

Generated On: 11 Jun 2021 14:57:14

SUBJECT WITH A HISTORY OF THROAT CANCER WAS CALLED ON 18AUG2020 FOR SAFETY CALL #3. SUBJECT REPORTED THAT DURING A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED AND HAS SPREAD TO THEIR LUNGS. PATIENT IS SCHEDULED FOR ONCOLOGY FOLLOW-UP ON 02SEP2020. MORE DETAILS, INCLUDING TREATMENT/PROCEDURES WILL BE REPORTED AS THE DATA BECOMES AVAILABLE. 9/24/2020 VISIT INFORMATION (ADDED FROM MEDICAL RECORDS RECEIVED 09OCT2020) DIAGNOSIS: SUBJECT IS DIAGNOSED WITH SQUAMOUS CELL CARCINOMA - LEFT TONSIL. STAGE: T2N2 (AJCC 8TH EDITION) T2N2C (7TH EDITION) MOLECULAR: P16+ GENE VARIANCE OF UNCERTAIN SIGNIFICANCE: CTNNB1: C.97T>A [P.SER33THR] CPS 2 ON CYCLE 1 OF PEMBROLIZUMAB. PLAN(DOCTOR'S NOTES): #SCC - LEFT TONSIL, T2N2 -NOW WITH BIOPSY PROVEN RECURRENT/METASTATIC DISEASE IN THE LUNGS -GIVEN LOW BURDEN, ASYMPTOMATIC DISEASE AND PD-L1 CPS 2, WILL PROCEED WITH FRONT LINE PEMBROLIZUMAB PER KN048

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)	

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Mar 2021 19:16:50

Generated On: 11 Jun 2021 14:57:14

AEID

Adverse event

INJECTION SITE PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

28 JUL 2020

Start time (00:00-23:59)

12:00 (24 HR)

AE start date and time (derived)

28 JUL 2020 12:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 AUG 2020

End time (00:00-23:59)

11:59 (24 HR)

AE End Date and Time (derived)

03 AUG 2020 11:59

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Mar 2021 19:16:50

Generated On: 11 Jun 2021 14:57:14

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:09:40

Generated On: 11 Jun 2021 14:57:14

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

Yes ☒

No ☐

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

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Mar 2021 20:40:31

Generated On: 11 Jun 2021 14:57:14

Name of Medication LIPITOR

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

137 of 1444

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Mar 2021 20:40:31

Generated On: 11 Jun 2021 14:57:14

	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 1990
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"/>

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Mar 2021 20:40:31

Generated On: 11 Jun 2021 14:57:14

Name of Medication PROBENECID

Prophylaxis Yes ☒
No ☐

Indication GOUT PREVENTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

139 of 1444

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Mar 2021 20:40:31

Generated On: 11 Jun 2021 14:57:14

	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 1996
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"/>

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Mar 2021 20:40:31

Generated On: 11 Jun 2021 14:57:14

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

141 of 1444

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Mar 2021 20:40:31

Generated On: 11 Jun 2021 14:57:14

	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 1975	
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"/>

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Mar 2021 20:40:31

Generated On: 11 Jun 2021 14:57:14

Name of Medication PEMBROLIZUMAB

Prophylaxis Yes ☐
No ☒

Indication THROAT CANCER ,
METASTASES TO LUNGS

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Mar 2021 20:40:31

Generated On: 11 Jun 2021 14:57:14

	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 checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 SEP 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3122010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:09:40

Generated On: 11 Jun 2021 14:57:14

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3122010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Mar 2021 18:54:42

Generated On: 11 Jun 2021 14:57:14

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 AUG 2020	CT CHEST WO CONTRAST IN IMG CT HBR	Adverse Event	
28 AUG 2020	GUIDED LUNG BIOPSY: POSITIVE FOR SQUAMOUS CELL CARCINOMA CONSISTENT WITH METASTASIS , CPS 2, P40/P16 AND HRHPV POSITIVE	Adverse Event	

US3122010

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

Date of dosing discontinuation (dd MMM yyyy)	18 AUG 2020
--	-------------

Primary reason for dosing discontinuation	AE (specify) <input checked="" type="radio"/>
	SAE (specify) <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-up <input type="radio"/>
	Physician decision (specify) <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol deviation (specify) <input type="radio"/>
	Study Terminated By Sponsor <input type="radio"/>
	Withdrawal of consent by participant (specify) <input type="radio"/>
	Due to SARS-COV-2 <input type="radio"/>
	Other <input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE#1
---	------

US3122010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 12 Mar 2021 20:47:49

Generated On: 11 Jun 2021 14:57:14

Date of study discontinuation/completion (dd MMM yyyy) 25 NOV 2020

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input checked="" type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

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

REOCCURRENCE OF THROAT CANCER RESULTED IN UNBLINDING. SUBJECT COULD CONTINUE SAFETY FOLLOW UP AT PHYSICIAN'S DISCRETION WHICH WAS REMOVED ON 11/25/20.

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	19/AUG/2020 13:10
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

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	25/AUG/2020 15:16
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

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	16/SEP/2020 15:01
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

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	01/OCT/2020 13:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	23/OCT/2020 20:40
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

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	23/NOV/2020 21:49
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

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	30/NOV/2020 15:04
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

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	16/FEB/2021 13:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	15/MAR/2021 11:26
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

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	16/MAR/2021 14:10
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

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	18/MAR/2021 11:54
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

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Data signed: (b) (4) 23 Mar 2021 19:16:51

Generated On: 11 Jun 2021 14:57:14

SAEID	USA-US063-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	23/MAR/2021 10:04
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

Audit

US3122010 (Prod: M3 Wake Research, Inc - M3 Wake)

US3122010

Form: Participant Creation

Generated On: 11 Jun 2021 14:57:14

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		16 Apr 2021 13:31:54
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User entered 'US3122010'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 14:19:31

US3122010

Form: Participant Creation

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:45:23
User entered 'Yes (Y)'	Leah Cortis (b) (4)	28 Jul 2020 19:30:46

US3122010

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:45:23
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 14:19:32

US3122010

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:45:23
User entered 'Clinic (Clinic)'	Leah Corts (b) (4)	28 Jul 2020 19:30:46

US3122010

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'SCRN'	System	28 Jul 2020 19:30:46

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 14:19:33

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered '62'	Leah Corts (b) (4)	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'YEARS'	System	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '62'	System	28 Jul 2020 19:32:29

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered 'Male (M)'	Leah Corts (b) (4)	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Leah Corts (b) (4)	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered 'I'	Leah Corts (b) (4)	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered '0'	Leah Corts (b) (4)	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered '0'	Leah Cortis (b) (4)	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered '0'	Leah Corts (b) (4)	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered '0'	Leah Corts (b) (4)	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered '0'	Leah Corts (b) (4)	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered empty.	Leah Corts (b) (4)	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered '0'	Leah Corts (b) (4)	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:57:14

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:10
User entered '0'	Leah Corts (b) (4)	28 Jul 2020 19:31:51

US3122010

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:57:14

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:56
User entered '27 Jul 2020'	Leah Corts (b) (4)	28 Jul 2020 19:32:29

US3122010

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Jul 2020'	System	28 Jul 2020 19:32:29

US3122010

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2020'	System	28 Jul 2020 19:32:29

US3122010

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:57:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:56
User entered 'Amendment 1 (1)'	Leah Corts (b) (4)	28 Jul 2020 19:32:29

US3122010

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:56
User entered 'Yes (Y)'	Leah Corts (b) (4)	28 Jul 2020 19:32:29

US3122010

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:56
User entered empty.	Leah Corts (b) (4)	28 Jul 2020 19:32:29

US3122010

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:57:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:56
User entered empty.	Leah Corts (b) (4)	28 Jul 2020 19:32:29

US3122010

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:57:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:56
User entered 'No (N)'	Leah Corts (b) (4)	28 Jul 2020 19:32:29

US3122010

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:57:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:54:56
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 14:19:32

US3122010

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:57:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'I'	System	28 Jul 2020 19:33:54

US3122010

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:03:26
User entered 'Yes (Y)'	Leah Corts (b) (4)	28 Jul 2020 19:33:54

US3122010

Folder: Screening

Form: Medical History Summary

Generated On: 11 Jun 2021 14:57:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:07
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:24:21

US3122010

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:57:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Salivary gland conditions, HLT: Oral dryness and saliva altered, PT: Dry mouth, LLT: Dry mouth - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:33:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:33:04
Data point term sent to Coder	System	30 Jul 2020 18:26:14
User entered 'Severe Dry Mouth'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:25:33

US3122010

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'un Apr 2019'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:25:33

US3122010

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:25:33

US3122010

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:57:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:25:33

US3122010

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered empty.	Aubrey Farray (b) (4)	30 Jul 2020 18:25:33

US3122010

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:57:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4)	30 Jul 2020 18:25:33

US3122010

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Apr 2019'	System	30 Jul 2020 18:25:33

US3122010

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2019'	System	30 Jul 2020 18:25:33

US3122010

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	30 Jul 2020 18:25:33

US3122010

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	30 Jul 2020 18:25:33

US3122010

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:57:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Respiratory tract and pleural neoplasms malignant cell type unspecified NEC, PT: Throat cancer, LLT: Throat cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jul 2020 18:28:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jul 2020 18:28:05
Data point term sent to Coder	System	30 Jul 2020 18:27:15
User entered 'Throat Cancer'	Aubrey Farrray (b) (4) (b) (4)	30 Jul 2020 18:26:19

US3122010

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'un Feb 2019'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:26:19

US3122010

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:26:19

US3122010

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:57:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:26:19

US3122010

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'un Jun 2019'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:26:19

US3122010

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:57:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:26:19

US3122010

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Feb 2019'	System	30 Jul 2020 18:26:19

US3122010

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2019'	System	30 Jul 2020 18:26:19

US3122010

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Jun 2019'	System	30 Jul 2020 18:26:19

US3122010

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2019'	System	30 Jul 2020 18:26:19

US3122010

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:57:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jul 2020 18:29:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jul 2020 18:29:23
Data point term sent to Coder	System	30 Jul 2020 18:28:15
User entered 'Pulmonary Embolism'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:27:49

US3122010

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '30 May 2019'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:27:49

US3122010

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:27:49

US3122010

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:57:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:27:49

US3122010

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '30 May 2019'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:27:49

US3122010

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:57:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:27:49

US3122010

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'May 2019'	System	30 Jul 2020 18:27:49

US3122010

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2019'	System	30 Jul 2020 18:27:49

US3122010

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'May 2019'	System	30 Jul 2020 18:27:49

US3122010

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2019'	System	30 Jul 2020 18:27:49

US3122010

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:57:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Influenza viral infections, PT: Influenza, LLT: Flu symptoms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 07:05:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 07:05:23
Data point term sent to Coder	System	30 Jul 2020 18:30:16
User entered 'Shingles Vaccine - Flu Symptoms'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:29:17

US3122010

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'un UNK 2019'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:29:17

US3122010

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:29:17

US3122010

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:57:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:29:17

US3122010

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'un UNK 2019'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:29:17

US3122010

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:57:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:29:17

US3122010

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Jan 2019'	System	30 Jul 2020 18:29:17

US3122010

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2019'	System	30 Jul 2020 18:29:17

US3122010

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Jan 2019'	System	30 Jul 2020 18:29:17

US3122010

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2019'	System	30 Jul 2020 18:29:17

US3122010

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:57:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria drug-induced - version MedDRA\\23.0.	Coder Import (b) (4)	29 Nov 2020 19:20:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Nov 2020 19:20:14
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 19:20:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jul 2020 18:41:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jul 2020 18:41:23
Data point term sent to Coder	System	30 Jul 2020 18:33:17
User entered 'Allergy to Hydrochlorothiazide - Hives'	Aubrey Farray (b) (4)	30 Jul 2020 18:32:59

US3122010

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'un UNK 2016'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:32:59

US3122010

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:32:59

US3122010

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:57:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:32:59

US3122010

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered empty.	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:32:59

US3122010

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:57:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:32:59

US3122010

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Jan 2016'	System	30 Jul 2020 18:32:59

US3122010

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2016'	System	30 Jul 2020 18:32:59

US3122010

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	30 Jul 2020 18:32:59

US3122010

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	30 Jul 2020 18:32:59

US3122010

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:57:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Jul 2020 18:53:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Jul 2020 18:53:11
Data point term sent to Coder	System	30 Jul 2020 18:34:17
User entered 'Kidney Stones Occasional'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:34:11

US3122010

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'un UNK 2004'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:34:11

US3122010

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:34:11

US3122010

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:57:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:34:11

US3122010

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered empty.	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:34:11

US3122010

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:57:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:34:11

US3122010

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Jan 2004'	System	30 Jul 2020 18:34:11

US3122010

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2004'	System	30 Jul 2020 18:34:11

US3122010

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	30 Jul 2020 18:34:11

US3122010

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	30 Jul 2020 18:34:11

US3122010

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:57:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms benign, HLT: Thyroid neoplasms benign, PT: Benign neoplasm of thyroid gland, LLT: Benign thyroid nodule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:43:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:43:10
Data point term sent to Coder	System	30 Jul 2020 18:38:20
User entered 'Thyroid Nodules - Benign'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:37:43

US3122010

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'un UNK 2019'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:37:43

US3122010

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:37:43

US3122010

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:57:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:37:43

US3122010

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered empty.	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:37:43

US3122010

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:57:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:37:43

US3122010

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Jan 2019'	System	30 Jul 2020 18:37:43

US3122010

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2019'	System	30 Jul 2020 18:37:43

US3122010

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	30 Jul 2020 18:37:43

US3122010

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	30 Jul 2020 18:37:43

US3122010

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 14:57:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Ear, nose and throat radiotherapies, PT: Radiation therapy to ear, nose, or throat, LLT: Radiation therapy to ear, nose, or throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:13:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:13:05
Data point term sent to Coder	System	30 Jul 2020 18:40:21
User entered 'Radiation therapy (for throat cancer)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:39:27

US3122010

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'un Mar 2019'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:39:27

US3122010

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:39:27

US3122010

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 14:57:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:39:27

US3122010

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'un Jun 2019'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:39:27

US3122010

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 14:57:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:39:27

US3122010

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Mar 2019'	System	30 Jul 2020 18:39:27

US3122010

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2019'	System	30 Jul 2020 18:39:27

US3122010

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Jun 2019'	System	30 Jul 2020 18:39:27

US3122010

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2019'	System	30 Jul 2020 18:39:27

US3122010

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:57:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Chemotherapies, PT: Chemotherapy, LLT: Chemotherapy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 10:58:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 10:58:03
Data point term sent to Coder	System	04 Aug 2020 10:57:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Chemotherapies, PT: Chemotherapy, LLT: Chemotherapy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 10:56:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 10:56:59
Query 'For coding purposes, please split to report each event separately to capture coding for all terms. Example: 1) CHEMOTHERAPY 2) THROAT CANCER' canceled (Site from System).	Coder Import (b) (4) (b) (4)	04 Aug 2020 10:56:52
User opened query 'For coding purposes, please split to report each event separately to capture coding for all terms. Example: 1) CHEMOTHERAPY 2) THROAT CANCER' (Site from System).	Coder Import (b) (4) (b) (4)	03 Aug 2020 15:40:58
Data point term sent to Coder	System	30 Jul 2020 18:41:23
User entered 'Chemotherapy (for throat cancer)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:40:52

US3122010

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'un Mar 2019'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:40:52

US3122010

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:40:52

US3122010

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:57:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:40:52

US3122010

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered 'un Jun 2019'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:40:52

US3122010

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:57:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:41
User entered '0'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:40:52

US3122010

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Mar 2019'	System	30 Jul 2020 18:40:52

US3122010

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2019'	System	30 Jul 2020 18:40:52

US3122010

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Jun 2019'	System	30 Jul 2020 18:40:52

US3122010

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '2019'	System	30 Jul 2020 18:40:52

US3122010

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:57:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 20:04:37
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 18:40:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 18:40:29
Data point term sent to Coder	System	25 Nov 2020 18:39:46
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	25 Nov 2020 18:39:07
DataPoint activated with code reason code Data required.		25 Nov 2020 18:38:43
DataPoint inactivated with code reason code Data not required.	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:41:17

US3122010

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:57:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User closed query 'Per source start year was 1970. Please review and update as needed.' (Site from CRA).		06 Apr 2021 14:53:56
DataPoint Verified.		06 Apr 2021 14:52:28
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
Query 'Per source start year was 1970. Please review and update as needed.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:53
User entered 'UN UNK 1970' reason for change:		12 Mar 2021 16:36:44
Data Entry Error		17 Feb 2021 20:04:41
DataPoint Un-verified.		17 Feb 2021 20:04:37
DataPoint Verified.		17 Feb 2021 20:04:37
User opened query 'Per source start year was 1970. Please review and update as needed.' (Site from CRA).		17 Feb 2021 20:02:10
Query 'Per source start year was 1970. ' canceled (Site from CRA).		17 Feb 2021 20:01:30
User opened query 'Per source start year was 1970. ' (Site from CRA).		17 Feb 2021 20:01:19
User entered 'UN UNK 1975'		25 Nov 2020 18:39:07
DataPoint activated with code reason code Data required.		25 Nov 2020 18:38:43
DataPoint inactivated with code reason code Data not required.	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:41:17

US3122010

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 20:04:37
User entered '0'		25 Nov 2020 18:39:07
DataPoint activated with code reason code Data required.		25 Nov 2020 18:38:43
DataPoint inactivated with code reason code Data not Aubrey Farray required.	(b) (4) (b) (4)	30 Jul 2020 18:41:17

US3122010

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:57:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 20:04:37
User entered 'Yes (Y)'		25 Nov 2020 18:39:07
DataPoint activated with code reason code Data required.		25 Nov 2020 18:38:43
DataPoint inactivated with code reason code Data not Aubrey Farray required.	(b) (4) (b) (4)	30 Jul 2020 18:41:17

US3122010

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 20:04:37
User entered empty.		25 Nov 2020 18:39:07
DataPoint activated with code reason code Data required.		25 Nov 2020 18:38:43
DataPoint inactivated with code reason code Data not Aubrey Farray required.	(b) (4) (b) (4)	30 Jul 2020 18:41:17

US3122010

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:57:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 20:04:37
User entered '0'		25 Nov 2020 18:39:07
DataPoint activated with code reason code Data required.		25 Nov 2020 18:38:43
DataPoint inactivated with code reason code Data not Aubrey Farray required.	(b) (4) (b) (4)	30 Jul 2020 18:41:17

US3122010

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'Jan 1970'	System	12 Mar 2021 16:36:44
User entered 'Jan 1975'	System	25 Nov 2020 18:39:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Nov 2020 18:38:43
DataPoint inactivated with code reason code Data not required.	Aubrey Farrah (b) (4) (b) (4)	30 Jul 2020 18:41:17

US3122010

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '1970'	System	12 Mar 2021 16:36:44
User entered '1975'	System	25 Nov 2020 18:39:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Nov 2020 18:38:43
DataPoint inactivated with code reason code Data not required.	Aubrey Farrah (b) (4) (b) (4)	30 Jul 2020 18:41:17

US3122010

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	25 Nov 2020 18:39:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Nov 2020 18:38:43
DataPoint inactivated with code reason code Data not required.	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:41:17

US3122010

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	25 Nov 2020 18:39:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	25 Nov 2020 18:38:43
DataPoint inactivated with code reason code Data not required.	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:41:17

US3122010

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:57:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 14:53:05
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
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.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 16:42:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 16:42:46
Data point term sent to Coder	System	12 Mar 2021 16:41:55
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	12 Mar 2021 16:41:10

US3122010

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 14:53:05
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	12 Mar 2021 16:41:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 16:41:15
User entered 'un ' (non-conformant).	System	12 Mar 2021 16:41:10
	(b) (4), (b) (6)	12 Mar 2021 16:41:10

US3122010

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 14:53:05
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'l'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:41:10

US3122010

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:57:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 14:53:05
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:41:10

US3122010

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 14:53:05
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:41:10

US3122010

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:57:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 14:53:05
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:41:10

US3122010

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 16:41:10

US3122010

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 16:41:10

US3122010

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 16:41:10

US3122010

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 16:41:10

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:24
User entered 'Yes (Y)'	Leah Corts (b) (4)	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:24
User entered '27 Jul 2020'	Leah Corts (b) (4)	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:24
User entered '10:40'	Leah Corts (b) (4)	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '27 Jul 2020 10:40'	System	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:24
User entered '71' in	Leah Corts (b) (4)	28 Jul 2020 19:35:17
DataPoint set to visible.	System	28 Jul 2020 19:33:54

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:24
User entered '182' lb	Leah Corts (b) (4)	28 Jul 2020 19:35:17
DataPoint set to visible.	System	28 Jul 2020 19:33:54

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: User entered '25.43692'	System	16 Sep 2020 23:36:44
User entered '25.4'	System	28 Jul 2020 19:35:17
DataPoint set to visible.	System	28 Jul 2020 19:33:54

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'kg/m2'	System	28 Jul 2020 19:35:17
DataPoint set to visible.	System	28 Jul 2020 19:33:54

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:13:49
User entered '97.8' F	Leah Corts (b) (4)	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:43:47
User closed query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 07:59:21
Query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	08 Sep 2020 14:36:24
DataPoint Un-verified.	Brad Killebrew (b) (4)	08 Sep 2020 14:36:17
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:36:17
User opened query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 10:40:28
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 19:10:24
User entered 'Other (Other)' reason for change: Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:13:49
User entered 'Oral (Oral)'	Leah Corts (b) (4)	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:43:47
User closed query 'Per CDM: Since Route of measurement is blank, please update "If Other, specify" field accordingly' (Site from DM).		11 Sep 2020 18:02:01
Query 'Per CDM: Since Route of measurement is blank, please update "If Other, specify" field accordingly' answered with 'complete ' (Site from DM).		10 Sep 2020 14:38:58
DataPoint Un-verified.		10 Sep 2020 14:38:54
User entered empty; reason for change Per Query Resolution		10 Sep 2020 14:38:54
User opened query 'Per CDM: Since Route of measurement is blank, please update "If Other, specify" field accordingly' (Site from DM).		10 Sep 2020 07:59:31
DataPoint Verified.		01 Sep 2020 19:10:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:13:49
User entered empty.	Leah Corts (b) (4)	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:13:49
User entered '56'	Leah Corts (b) (4)	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'bpm'	System	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:13:49
User entered '12'	Leah Corts (b) (4)	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'breaths/min'	System	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:13:49
User entered '147'	Leah Corts (b) (4)	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'mmHg'	System	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:13:49
User entered '83'	Leah Corts (b) (4)	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'mmHg'	System	28 Jul 2020 19:35:17

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 14:57:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:11:31
User entered 'Yes (Y)'	Leah Corts (b) (4)	28 Jul 2020 19:36:07

US3122010

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 14:57:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Sep 2020 19:11:31
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).		27 Aug 2020 11:59:49
Comment added 'This Date is Correct'.	Leah Corts (b) (4)	25 Aug 2020 17:50:15
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		25 Aug 2020 16:22:54
User entered '27 Jul 2020'	Leah Corts (b) (4)	28 Jul 2020 19:36:07

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

[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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

[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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

[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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

[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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'Yes (Y)'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered 'Retired'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User entered 'I'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered '0'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered '0'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

[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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered '0'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered '0'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered '0'	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:57:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:53:48
User entered empty.	Leah Corts (b) (4)	24 Aug 2020 18:48:14

US3122010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:51:53
User entered 'Yes (Y)'	Leah Corts (b) (4)	28 Jul 2020 19:36:27

US3122010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:51:53
User entered '27 Jul 2020'	Leah Corts (b) (4)	28 Jul 2020 19:36:27

US3122010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:51:53
User entered 'Clinic (Clinic)'	Leah Corts (b) (4)	28 Jul 2020 19:36:27

US3122010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'VISIT1'	System	28 Jul 2020 19:36:27

US3122010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:23:49
DataPoint Un-verified.		01 Sep 2020 19:12:20
DataPoint Verified.		01 Sep 2020 19:11:51
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 15:19:46

US3122010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:57:14

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:23:50
DataPoint Un-verified.		01 Sep 2020 19:12:18
DataPoint Verified.		01 Sep 2020 19:11:51
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:01:19
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:01:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Jul 2020 15:19:46
User entered '142026' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 15:19:46

US3122010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:57:14

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Oct 2020 22:13:03
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from DM).		02 Oct 2020 22:13:01
DataPoint Verified.		02 Oct 2020 20:21:15
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'unable to change at this point' (Site from System).	Brad Killebrew (b) (4)	01 Oct 2020 15:53:35
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 20:57:39
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'Pt is listed at risk due to their profession.' (Site from DM).	Leah Corts (b) (4)	30 Sep 2020 18:42:12
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 15:58:24
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' canceled (Site from System).		30 Sep 2020 15:58:15
DataPoint Un-verified.		01 Sep 2020 19:12:17
DataPoint Verified.		01 Sep 2020 19:11:51
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Jul 2020 18:44:10
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 15:19:46

US3122010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:57:14

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:21:15
DataPoint Un-verified.		01 Sep 2020 19:24:04
DataPoint Verified.		01 Sep 2020 19:11:51
User entered 'No (N)'	Aubrey Farrey (b) (4) (b) (4)	30 Jul 2020 18:44:10

US3122010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:57:14

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:21:15
DataPoint Un-verified.		01 Sep 2020 19:24:01
DataPoint Verified.		01 Sep 2020 19:11:51
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:44:10

US3122010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:57:14

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:11:51
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:44:10

US3122010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:57:14

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:11:51
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:44:10

US3122010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:57:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:11:51
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:44:10

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:57:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:14:19
User entered '71' in	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:57:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:14:19
User entered '182' lb	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:57:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:14:19
User entered '71' in	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:57:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:14:19
User entered '182' lb	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User accepted default value 'Pre-Dose (PREDOSE)'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered 'Yes (Y)'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '27 Jul 2020'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '10:40'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '27 Jul 2020 10:40'	System	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '97.8' F	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered 'Oral (Oral)'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered empty.	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '56'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'bpm'	System	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '12'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'breaths/min'	System	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '147'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'mmHg'	System	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '83'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'mmHg'	System	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:57:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:14:19
User entered '71' in	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:57:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 19:14:19
User entered '182' lb	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User accepted default value 'Post-Dose (POSTDOSE)'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered 'Yes (Y)'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '27 Jul 2020'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 15:34:47
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		28 Jul 2020 19:39:27
User entered '12:35'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '27 Jul 2020 12:35'	System	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '36.4' C	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered 'Oral (Oral)'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered empty.	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '60'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'bpm'	System	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '18'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'breaths/min'	System	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '152'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'mmHg'	System	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:31
User entered '86'	Leah Corts (b) (4)	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'mmHg'	System	28 Jul 2020 19:38:36

US3122010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 14:57:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:44
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:45:50

US3122010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 14:57:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:44
User entered empty.	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 18:45:50

US3122010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:08
User entered 'Yes (Y)'	Leah Corts (b) (4)	28 Jul 2020 19:39:27

US3122010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:08
User entered empty.	Leah Corts (b) (4)	28 Jul 2020 19:39:27

US3122010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:08
User entered empty.	Leah Corts (b) (4)	28 Jul 2020 19:39:27

US3122010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'MRNA-1273 OR PLACEBO'	System	28 Jul 2020 19:39:27

US3122010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:08
User entered '27 Jul 2020'	Leah Corts (b) (4)	28 Jul 2020 19:39:27

US3122010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:08
User entered '12:03'	Leah Corts (b) (4)	28 Jul 2020 19:39:27

US3122010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '27 Jul 2020 12:03'	System	28 Jul 2020 19:39:27

US3122010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:08
User entered 'Left Arm (LEFT ARM)'	Leah Corts (b) (4)	28 Jul 2020 19:39:27

US3122010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		01 Sep 2020 19:44:08
User entered 'ONCE'	System	28 Jul 2020 19:39:27

US3122010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'INTRAMUSCULAR'	System	28 Jul 2020 19:39:27

US3122010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:45:20
User entered 'Yes (Y)'	Leah Corts (b) (4)	28 Jul 2020 19:40:03

US3122010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:45:20
User entered '27 Jul 2020'	Leah Corts (b) (4)	28 Jul 2020 19:40:03

US3122010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:45:20
User entered '11:29'	Leah Corts (b) (4)	28 Jul 2020 19:40:03

US3122010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '27 Jul 2020 11:29'	System	28 Jul 2020 19:40:03

US3122010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 14:57:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:45:31
User entered '27 Jul 2020'	Leah Corts (b) (4)	28 Jul 2020 19:40:24

US3122010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:57:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Leah Corts (b) (4)	28 Jul 2020 19:40:24

US3122010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:57:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:45:31
User entered 'Yes (Y)'	Leah Corts (b) (4)	28 Jul 2020 19:40:24

US3122010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:57:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:45:31
User entered '11:32'	Leah Corts (b) (4)	28 Jul 2020 19:40:24

US3122010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:57:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '27 Jul 2020 11:32'	System	28 Jul 2020 19:40:24

US3122010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:57:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Leah Corts (b) (4)	28 Jul 2020 19:40:24

US3122010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:57:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:45:31
User entered 'No (N)'	Leah Corts (b) (4)	28 Jul 2020 19:40:24

US3122010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:57:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:45:31
User entered empty.	Leah Corts (b) (4)	28 Jul 2020 19:40:24

US3122010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:57:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	28 Jul 2020 19:40:24

US3122010

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:47:05
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:56:31

US3122010

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'I'	System	13 Aug 2020 18:56:31

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '27 Jul 2020 12:23'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '27 Jul 2020 14:53'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '27 Jul 2020 15:48'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 2'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:57:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:23:50', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b69e90a2-3c9e-40b4-b6f8-e7324a496baa' User entered 'Yes (Y)'	System	28 Jul 2020 23:24:24
	System	28 Jul 2020 23:24:24

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:57:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:24:08', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b69e90a2-3c9e-40b4-b6f8-e7324a496baa' User entered '98.3'	System	28 Jul 2020 23:24:24
	System	28 Jul 2020 23:24:24

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:24:12', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b69e90a2-3c9e-40b4-b6f8-e7324a496baa' User entered 'No (N)'	System	28 Jul 2020 23:24:24
	System	28 Jul 2020 23:24:24

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:24:22', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b69e90a2-3c9e-40b4-b6f8-e7324a496baa' User entered '28 Jul 2020 19:24'	System	28 Jul 2020 23:24:24
	System	28 Jul 2020 23:24:24

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 3'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:57:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:46:57', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '2db26eee-f0be-4948-9f41-d1e9e8d1cbbc' User entered 'Yes (Y)'	System	29 Jul 2020 22:47:23
	System	29 Jul 2020 22:47:23

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:57:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:47:04', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '2db26eee-f0be-4948-9f41-d1e9e8d1cbbc' User entered '98.3'	System	29 Jul 2020 22:47:23
	System	29 Jul 2020 22:47:23

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:47:10', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '2db26eee-f0be-4948-9f41-d1e9e8d1cbbc'	System	29 Jul 2020 22:47:23
User entered 'No (N)'	System	29 Jul 2020 22:47:23

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:47:20', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '2db26eee-f0be-4948-9f41-d1e9e8d1cbbc' User entered '29 Jul 2020 18:47'	System	29 Jul 2020 22:47:23
	System	29 Jul 2020 22:47:23

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 4'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:57:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:31:56', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '839ec660-8333-4607-8383-624824bce1c3'	System	30 Jul 2020 17:32:16
User entered 'Yes (Y)'	System	30 Jul 2020 17:32:16

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:57:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:32:02', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '839ec660-8333-4607-8383-624824bce1c3' User entered '97.4'	System	30 Jul 2020 17:32:16
	System	30 Jul 2020 17:32:16

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:32:08', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '839ec660-8333-4607-8383-624824bce1c3'	System	30 Jul 2020 17:32:16
User entered 'No (N)'	System	30 Jul 2020 17:32:16

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:32:14', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '839ec660-8333-4607-8383-624824bce1c3' User entered '30 Jul 2020 13:32'	System	30 Jul 2020 17:32:16
	System	30 Jul 2020 17:32:16

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 5'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:57:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:41:21', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'ab447a5a-b0d8-4418-b251-7e2b23a3e2f6' User entered 'Yes (Y)'	System	31 Jul 2020 19:41:46
	System	31 Jul 2020 19:41:46

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:57:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:41:28', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'ab447a5a-b0d8-4418-b251-7e2b23a3e2f6' User entered '98.8'	System	31 Jul 2020 19:41:46
	System	31 Jul 2020 19:41:46

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:41:33', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'ab447a5a-b0d8-4418-b251-7e2b23a3e2f6'	System	31 Jul 2020 19:41:46
User entered 'No (N)'	System	31 Jul 2020 19:41:46

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:41:43', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'ab447a5a-b0d8-4418-b251-7e2b23a3e2f6' User entered '31 Jul 2020 15:41'	System	31 Jul 2020 19:41:46
	System	31 Jul 2020 19:41:46

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 6'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:57:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:08:26', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'de93a22c-a373-4723-ac8b-ffa26594eef1' User entered 'Yes (Y)'	System	01 Aug 2020 16:08:50
	System	01 Aug 2020 16:08:50

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:57:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:08:33', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'de93a22c-a373-4723-ac8b-ffa26594eef1' User entered '97.9'	System	01 Aug 2020 16:08:50
	System	01 Aug 2020 16:08:50

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:08:37', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'de93a22c-a373-4723-ac8b-ffa26594eef1' User entered 'No (N)'	System	01 Aug 2020 16:08:50
	System	01 Aug 2020 16:08:50

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:08:48', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'de93a22c-a373-4723-ac8b-ffa26594eef1' User entered '01 Aug 2020 12:08'	System	01 Aug 2020 16:08:50
	System	01 Aug 2020 16:08:50

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 7'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:57:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:13:34', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9374b4a9-64c9-4e49-9d95-7edc3b8f9e33'	System	03 Aug 2020 01:13:55
User entered 'Yes (Y)'	System	03 Aug 2020 01:13:55

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:57:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:13:43', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9374b4a9-64c9-4e49-9d95-7edc3b8f9e33' User entered '98.4'	System	03 Aug 2020 01:13:55
	System	03 Aug 2020 01:13:55

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:13:48', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9374b4a9-64c9-4e49-9d95-7edc3b8f9e33'	System	03 Aug 2020 01:13:55
User entered 'No (N)'	System	03 Aug 2020 01:13:55

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:13:54', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9374b4a9-64c9-4e49-9d95-7edc3b8f9e33'	System	03 Aug 2020 01:13:55
User entered '02 Aug 2020 21:13'	System	03 Aug 2020 01:13:55

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '27 Jul 2020 12:23'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '27 Jul 2020 14:53'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '27 Jul 2020 15:48'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 2'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:25:01', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'cf4f6b02-d0a5-4880-93d2-02fc4be9c4a5'	System	28 Jul 2020 23:25:41
User entered 'Does not interfere with activity (2)'	System	28 Jul 2020 23:25:41

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:57:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:25:04', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'cf4f6b02-d0a5-4880-93d2-02fc4be9c4a5' User entered 'No (N)'	System	28 Jul 2020 23:25:41
	System	28 Jul 2020 23:25:41

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:25:09', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'cf4f6b02-d0a5-4880-93d2-02fc4be9c4a5' User entered 'No (N)'	System	28 Jul 2020 23:25:41
	System	28 Jul 2020 23:25:41

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:25:23', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'cf4f6b02-d0a5-4880-93d2-02fc4be9c4a5'	System	28 Jul 2020 23:25:41
User entered 'None (1)'	System	28 Jul 2020 23:25:41

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:25:39', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'cf4f6b02-d0a5-4880-93d2-02fc4be9c4a5'	System	28 Jul 2020 23:25:41
User entered '28 Jul 2020 19:25'	System	28 Jul 2020 23:25:41

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 3'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:46:29', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '17cdec64-f9ec-46d1-b93f-85b412cedbc3'	System	29 Jul 2020 22:46:44
User entered 'Does not interfere with activity (2)'	System	29 Jul 2020 22:46:44

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:57:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:45:30', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '17cdec64-f9ec-46d1-b93f-85b412cedbc3' User entered 'Yes (Y)'	System	29 Jul 2020 22:46:44
	System	29 Jul 2020 22:46:44

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:57:14

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:45:52', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '17cdec64-f9ec-46d1-b93f-85b412cedbc3' User entered '50'	System	29 Jul 2020 22:46:44
	System	29 Jul 2020 22:46:44

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:45:58', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '17cdec64-f9ec-46d1-b93f-85b412cedbc3' User entered 'No (N)'	System	29 Jul 2020 22:46:44
	System	29 Jul 2020 22:46:44

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:46:06', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '17cdec64-f9ec-46d1-b93f-85b412cedbc3'	System	29 Jul 2020 22:46:44
User entered 'None (1)'	System	29 Jul 2020 22:46:44

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:46:42', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '17cdec64-f9ec-46d1-b93f-85b412cedbc3' User entered '29 Jul 2020 18:46'	System	29 Jul 2020 22:46:44
	System	29 Jul 2020 22:46:44

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 4'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:26:35', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9a81a040-2a17-46fc-ae5c-5df49b42b32d' User entered 'Does not interfere with activity (2)'	System	30 Jul 2020 17:27:05
	System	30 Jul 2020 17:27:05

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:57:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:26:38', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9a81a040-2a17-46fc-ae5c-5df49b42b32d' User entered 'No (N)'	System	30 Jul 2020 17:27:05
	System	30 Jul 2020 17:27:05

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:26:43', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9a81a040-2a17-46fc-ae5c-5df49b42b32d' User entered 'No (N)'	System	30 Jul 2020 17:27:05
	System	30 Jul 2020 17:27:05

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:26:50', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9a81a040-2a17-46fc-ae5c-5df49b42b32d' User entered 'None (1)'	System	30 Jul 2020 17:27:05
	System	30 Jul 2020 17:27:05

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:27:02', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9a81a040-2a17-46fc-ae5c-5df49b42b32d' User entered '30 Jul 2020 13:27'	System	30 Jul 2020 17:27:05
	System	30 Jul 2020 17:27:05

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 5'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:41:57', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b52fcf64-7655-4507-a836-c7236b430a90'	System	31 Jul 2020 19:42:15
User entered 'Does not interfere with activity (2)'	System	31 Jul 2020 19:42:15

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:57:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:42:02', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b52fcf64-7655-4507-a836-c7236b430a90' User entered 'No (N)'	System	31 Jul 2020 19:42:15
	System	31 Jul 2020 19:42:15

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:42:05', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b52fcf64-7655-4507-a836-c7236b430a90' User entered 'No (N)'	System	31 Jul 2020 19:42:15
	System	31 Jul 2020 19:42:15

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:42:08', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b52fcf64-7655-4507-a836-c7236b430a90'	System	31 Jul 2020 19:42:15
User entered 'None (1)'	System	31 Jul 2020 19:42:15

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:42:13', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b52fcf64-7655-4507-a836-c7236b430a90' User entered '31 Jul 2020 15:42'	System	31 Jul 2020 19:42:15
	System	31 Jul 2020 19:42:15

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 6'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:09:21', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '86dad289-44f0-4214-a66e-07c7a7378068' User entered 'None (1)'	System	01 Aug 2020 16:09:39
	System	01 Aug 2020 16:09:39

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:57:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:09:24', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '86dad289-44f0-4214-a66e-07c7a7378068' User entered 'No (N)'	System	01 Aug 2020 16:09:39
	System	01 Aug 2020 16:09:39

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:09:27', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '86dad289-44f0-4214-a66e-07c7a7378068' User entered 'No (N)'	System	01 Aug 2020 16:09:39
	System	01 Aug 2020 16:09:39

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:09:30', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '86dad289-44f0-4214-a66e-07c7a7378068' User entered 'None (1)'	System	01 Aug 2020 16:09:39
	System	01 Aug 2020 16:09:39

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:09:35', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '86dad289-44f0-4214-a66e-07c7a7378068' User entered '01 Aug 2020 12:09'	System	01 Aug 2020 16:09:39
	System	01 Aug 2020 16:09:39

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 7'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:01', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '7da35df7-27c6-4a93-be74-cab6ee91969f'	System	03 Aug 2020 01:14:22
User entered 'Does not interfere with activity (2)'	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:57:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:04', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '7da35df7-27c6-4a93-be74-cab6ee91969f' User entered 'No (N)'	System	03 Aug 2020 01:14:22
	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:10', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '7da35df7-27c6-4a93-be74-cab6ee91969f' User entered 'No (N)'	System	03 Aug 2020 01:14:22
	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:14', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '7da35df7-27c6-4a93-be74-cab6ee91969f' User entered 'None (1)'	System	03 Aug 2020 01:14:22
	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:19', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '7da35df7-27c6-4a93-be74-cab6ee91969f' User entered '02 Aug 2020 21:14'	System	03 Aug 2020 01:14:22
	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '27 Jul 2020 12:23'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '27 Jul 2020 14:53'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '27 Jul 2020 15:48'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 2'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:25:49', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9ad56a86-3e23-45df-93bb-acc71a473374' User entered 'None (0)'	System	28 Jul 2020 23:26:40
	System	28 Jul 2020 23:26:40

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:25:54', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9ad56a86-3e23-45df-93bb-acc71a473374' User entered 'None (0)'	System	28 Jul 2020 23:26:40
	System	28 Jul 2020 23:26:40

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:26:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9ad56a86-3e23-45df-93bb-acc71a473374' User entered 'None (0)'	System	28 Jul 2020 23:26:40
	System	28 Jul 2020 23:26:40

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:26:04', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9ad56a86-3e23-45df-93bb-acc71a473374' User entered 'None (0)'	System	28 Jul 2020 23:26:40
	System	28 Jul 2020 23:26:40

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:26:07', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9ad56a86-3e23-45df-93bb-acc71a473374' User entered 'None (0)'	System	28 Jul 2020 23:26:40
	System	28 Jul 2020 23:26:40

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:26:11', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9ad56a86-3e23-45df-93bb-acc71a473374' User entered 'None (0)'	System	28 Jul 2020 23:26:40
	System	28 Jul 2020 23:26:40

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:26:15', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9ad56a86-3e23-45df-93bb-acc71a473374' User entered 'No (N)'	System	28 Jul 2020 23:26:40
	System	28 Jul 2020 23:26:40

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-28T19:26:38', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9ad56a86-3e23-45df-93bb-acc71a473374' User entered '28 Jul 2020 19:26'	System	28 Jul 2020 23:26:40
	System	28 Jul 2020 23:26:40

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 3'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:47:29', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '22c3dbf3-6042-4aa5-b0eb-b56703cb8c89' User entered 'None (0)'	System	29 Jul 2020 22:48:32
	System	29 Jul 2020 22:48:32

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:47:35', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '22c3dbf3-6042-4aa5-b0eb-b56703cb8c89' User entered 'None (0)'	System	29 Jul 2020 22:48:32
	System	29 Jul 2020 22:48:32

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:47:44', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '22c3dbf3-6042-4aa5-b0eb-b56703cb8c89' User entered 'None (0)'	System	29 Jul 2020 22:48:32
	System	29 Jul 2020 22:48:32

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:47:53', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '22c3dbf3-6042-4aa5-b0eb-b56703cb8c89' User entered 'None (0)'	System	29 Jul 2020 22:48:32
	System	29 Jul 2020 22:48:32

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:47:55', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '22c3dbf3-6042-4aa5-b0eb-b56703cb8c89' User entered 'None (0)'	System	29 Jul 2020 22:48:32
	System	29 Jul 2020 22:48:32

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:47:58', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '22c3dbf3-6042-4aa5-b0eb-b56703cb8c89' User entered 'None (0)'	System	29 Jul 2020 22:48:32
	System	29 Jul 2020 22:48:32

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:48:04', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '22c3dbf3-6042-4aa5-b0eb-b56703cb8c89' User entered 'No (N)'	System	29 Jul 2020 22:48:32
	System	29 Jul 2020 22:48:32

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-29T18:48:28', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '22c3dbf3-6042-4aa5-b0eb-b56703cb8c89' User entered '29 Jul 2020 18:48'	System	29 Jul 2020 22:48:32
	System	29 Jul 2020 22:48:32

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 4'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:27:09', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'e166c88c-b5c2-4ee7-9146-6a2ed16ba898' User entered 'None (0)'	System	30 Jul 2020 17:28:03
	System	30 Jul 2020 17:28:03

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:27:18', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'e166c88c-b5c2-4ee7-9146-6a2ed16ba898'	System	30 Jul 2020 17:28:03
User entered 'No interference with activity (1)'	System	30 Jul 2020 17:28:03

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:27:40', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'e166c88c-b5c2-4ee7-9146-6a2ed16ba898' User entered 'None (0)'	System	30 Jul 2020 17:28:03
	System	30 Jul 2020 17:28:03

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:27:46', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'e166c88c-b5c2-4ee7-9146-6a2ed16ba898' User entered 'None (0)'	System	30 Jul 2020 17:28:03
	System	30 Jul 2020 17:28:03

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:27:50', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'e166c88c-b5c2-4ee7-9146-6a2ed16ba898' User entered 'None (0)'	System	30 Jul 2020 17:28:03
	System	30 Jul 2020 17:28:03

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:27:53', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'e166c88c-b5c2-4ee7-9146-6a2ed16ba898' User entered 'None (0)'	System	30 Jul 2020 17:28:03
	System	30 Jul 2020 17:28:03

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:27:56', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'e166c88c-b5c2-4ee7-9146-6a2ed16ba898' User entered 'No (N)'	System	30 Jul 2020 17:28:03
	System	30 Jul 2020 17:28:03

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-30T13:28:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'e166c88c-b5c2-4ee7-9146-6a2ed16ba898' User entered '30 Jul 2020 13:28'	System	30 Jul 2020 17:28:03
	System	30 Jul 2020 17:28:03

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 5'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:42:19', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '66c4de0f-9179-47d1-950f-3c5d418ca653' User entered 'None (0)'	System	31 Jul 2020 19:42:43
	System	31 Jul 2020 19:42:43

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:42:23', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '66c4de0f-9179-47d1-950f-3c5d418ca653'	System	31 Jul 2020 19:42:43
User entered 'No interference with activity (1)'	System	31 Jul 2020 19:42:43

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:42:25', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '66c4de0f-9179-47d1-950f-3c5d418ca653' User entered 'None (0)'	System	31 Jul 2020 19:42:43
	System	31 Jul 2020 19:42:43

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:42:28', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '66c4de0f-9179-47d1-950f-3c5d418ca653' User entered 'None (0)'	System	31 Jul 2020 19:42:43
	System	31 Jul 2020 19:42:43

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:42:30', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '66c4de0f-9179-47d1-950f-3c5d418ca653' User entered 'None (0)'	System	31 Jul 2020 19:42:43
	System	31 Jul 2020 19:42:43

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:42:33', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '66c4de0f-9179-47d1-950f-3c5d418ca653' User entered 'None (0)'	System	31 Jul 2020 19:42:43
	System	31 Jul 2020 19:42:43

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:42:37', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '66c4de0f-9179-47d1-950f-3c5d418ca653' User entered 'No (N)'	System	31 Jul 2020 19:42:43
	System	31 Jul 2020 19:42:43

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-07-31T15:42:41', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '66c4de0f-9179-47d1-950f-3c5d418ca653' User entered '31 Jul 2020 15:42'	System	31 Jul 2020 19:42:43
	System	31 Jul 2020 19:42:43

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 6'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:09:40', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '5688fee2-f415-4810-b77f-e88e071b5aea' User entered 'None (0)'	System	01 Aug 2020 16:10:11
	System	01 Aug 2020 16:10:11

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:09:43', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '5688fee2-f415-4810-b77f-e88e071b5aea' User entered 'None (0)'	System	01 Aug 2020 16:10:11
	System	01 Aug 2020 16:10:11

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:09:45', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '5688fee2-f415-4810-b77f-e88e071b5aea' User entered 'None (0)'	System	01 Aug 2020 16:10:11
	System	01 Aug 2020 16:10:11

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:09:46', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '5688fee2-f415-4810-b77f-e88e071b5aea' User entered 'None (0)'	System	01 Aug 2020 16:10:11
	System	01 Aug 2020 16:10:11

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:09:48', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '5688fee2-f415-4810-b77f-e88e071b5aea' User entered 'None (0)'	System	01 Aug 2020 16:10:11
	System	01 Aug 2020 16:10:11

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:09:50', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '5688fee2-f415-4810-b77f-e88e071b5aea' User entered 'None (0)'	System	01 Aug 2020 16:10:11
	System	01 Aug 2020 16:10:11

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:09:55', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '5688fee2-f415-4810-b77f-e88e071b5aea' User entered 'No (N)'	System	01 Aug 2020 16:10:11
	System	01 Aug 2020 16:10:11

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-01T12:10:07', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '5688fee2-f415-4810-b77f-e88e071b5aea' User entered '01 Aug 2020 12:10'	System	01 Aug 2020 16:10:11
	System	01 Aug 2020 16:10:11

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 7'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:25', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '380a4307-e1b8-4d23-9d1b-c7b2fcd78430' User entered 'None (0)'	System	03 Aug 2020 01:14:49
	System	03 Aug 2020 01:14:49

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:29', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '380a4307-e1b8-4d23-9d1b-c7b2fcd78430' User entered 'None (0)'	System	03 Aug 2020 01:14:49
	System	03 Aug 2020 01:14:49

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:32', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '380a4307-e1b8-4d23-9d1b-c7b2fcd78430' User entered 'None (0)'	System	03 Aug 2020 01:14:49
	System	03 Aug 2020 01:14:49

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:34', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '380a4307-e1b8-4d23-9d1b-c7b2fcd78430' User entered 'None (0)'	System	03 Aug 2020 01:14:49
	System	03 Aug 2020 01:14:49

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:37', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '380a4307-e1b8-4d23-9d1b-c7b2fcd78430' User entered 'None (0)'	System	03 Aug 2020 01:14:49
	System	03 Aug 2020 01:14:49

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:39', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '380a4307-e1b8-4d23-9d1b-c7b2fcd78430' User entered 'None (0)'	System	03 Aug 2020 01:14:49
	System	03 Aug 2020 01:14:49

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:43', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '380a4307-e1b8-4d23-9d1b-c7b2fcd78430' User entered 'No (N)'	System	03 Aug 2020 01:14:49
	System	03 Aug 2020 01:14:49

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-02T21:14:46', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '380a4307-e1b8-4d23-9d1b-c7b2fcd78430' User entered '02 Aug 2020 21:14'	System	03 Aug 2020 01:14:49
	System	03 Aug 2020 01:14:49

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	03 Aug 2020 01:14:22
User entered 'Day 8'	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-03T12:02:07', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b7de0fe9-171a-4ca6-9523-bc06461181c4'	System	03 Aug 2020 16:02:19
User entered 'Does not interfere with activity (2)'	System	03 Aug 2020 16:02:19

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-03T12:02:15', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b7de0fe9-171a-4ca6-9523-bc06461181c4' User entered '03 Aug 2020 12:02'	System	03 Aug 2020 16:02:19
	System	03 Aug 2020 16:02:19

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '03 Aug 2020 12:00'	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	03 Aug 2020 01:14:22
User entered 'Day 9'	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Jun 2021 14:57:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-04T21:13:16', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '6a213678-38d4-4e30-be23-efd56884e126' User entered 'None (1)'	System	05 Aug 2020 01:13:23
	System	05 Aug 2020 01:13:23

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Jun 2021 14:57:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-04T21:13:20', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '6a213678-38d4-4e30-be23-efd56884e126' User entered '04 Aug 2020 21:13'	System	05 Aug 2020 01:13:23
	System	05 Aug 2020 01:13:23

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	03 Aug 2020 01:14:22
User entered 'Day 8'	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-03T12:02:23', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'c0140e05-cbec-4475-b88f-4c3aae8b55fc' User entered 'No (N)'	System	03 Aug 2020 16:02:30
	System	03 Aug 2020 16:02:30

US3122010

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Jun 2021 14:57:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-03T12:02:28', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'c0140e05-cbec-4475-b88f-4c3aae8b55fc' User entered '03 Aug 2020 12:02'	System	03 Aug 2020 16:02:30
	System	03 Aug 2020 16:02:30

US3122010

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '03 Aug 2020 12:00'	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	03 Aug 2020 01:14:22
User entered 'Day 9'	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-04T21:13:27', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'dbdb2ec2-c50e-49b5-975e-94ac32447795' User entered 'No (N)'	System	05 Aug 2020 01:13:35
	System	05 Aug 2020 01:13:35

US3122010

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Jun 2021 14:57:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-08-04T21:13:31', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'dbdb2ec2-c50e-49b5-975e-94ac32447795' User entered '04 Aug 2020 21:13'	System	05 Aug 2020 01:13:35
	System	05 Aug 2020 01:13:35

US3122010

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Jun 2021 14:57:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 01:14:22

US3122010

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Jun 2021 14:57:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 01:14:22

US3122010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:55:18
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:57:02

US3122010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:55:18
User entered '5 Aug 2020'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:57:02

US3122010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:55:18
User entered 'Contact Made (CONTACT MADE)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:57:02

US3122010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:55:18
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:57:02

US3122010

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:55:29
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:57:06

US3122010

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'I'	System	13 Aug 2020 18:57:06

US3122010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:55:49
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:57:27

US3122010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:55:49
User entered '10 Aug 2020'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:57:27

US3122010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:55:49
User entered 'Contact Made (CONTACT MADE)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:57:27

US3122010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:55:49
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:57:27

US3122010

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:55:54
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:57:38

US3122010

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'I'	System	13 Aug 2020 18:57:38

US3122010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:03:52
User entered 'Yes (Y)'	Leah Corts (b) (4)	24 Aug 2020 20:17:02

US3122010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:03:52
User entered '18 Aug 2020'	Leah Corts (b) (4)	24 Aug 2020 20:17:02

US3122010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:03:52
User entered 'Contact Made (CONTACT MADE)'	Leah Corts (b) (4)	24 Aug 2020 20:17:02

US3122010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:03:52
User entered empty.	Leah Corts (b) (4)	24 Aug 2020 20:17:02

US3122010

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:04:08
User entered 'Yes (Y)'	Leah Corts (b) (4)	24 Aug 2020 20:17:26

US3122010

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'I'	System	24 Aug 2020 20:17:26

US3122010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21sep2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:58:05
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21sep2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'this has been updated in EDC' (Site from DM).		09 Nov 2020 16:32:48
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21sep2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).		30 Oct 2020 08:53:32
DataPoint Verified.		01 Sep 2020 20:04:21
User entered 'Yes (Y)'	Leah Cortis (b) (4)	25 Aug 2020 16:22:54

US3122010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:04:21
User entered '25 Aug 2020'	Leah Corts (b) (4)	25 Aug 2020 16:22:54

US3122010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:04:21
User entered 'Clinic (Clinic)'	Leah Corts (b) (4)	25 Aug 2020 16:22:54

US3122010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'VISIT2'	System	25 Aug 2020 16:22:54

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User accepted default value 'Pre-Dose (PREDOSE)'	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered 'Yes (Y)'	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered '25 Aug 2020'	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:56:10
User closed query 'per source vitals were done at 9:30. Please review and update as needed. ' (Site from CRA).		17 Feb 2021 19:56:05
Query 'per source vitals were done at 9:30. Please review and update as needed. ' answered with 'updated' (Site from CRA).	Brad Killebrew (b) (4)	15 Sep 2020 14:00:44
User entered '09:30' reason for change: Data Entry Error	Brad Killebrew (b) (4)	15 Sep 2020 14:00:35
DataPoint Un-verified.	(b) (4), (b) (6)	01 Sep 2020 20:08:22
DataPoint Verified.		01 Sep 2020 20:08:20
User opened query 'per source vitals were done at 9:30. Please review and update as needed. ' (Site from CRA).		01 Sep 2020 20:05:30
User entered '10:40'	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '25 Aug 2020 09:30'	System	15 Sep 2020 14:00:35
User entered '25 Aug 2020 10:40'	System	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User closed query 'per source temp is 98.3. Please review and update as needed. ' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:56:39 17 Feb 2021 19:56:10
Query 'per source temp is 98.3. Please review and update as needed. ' answered with 'updated' (Site from CRA). DataPoint Un-verified.	Brad Killebrew (b) (4)	15 Sep 2020 14:00:48 15 Sep 2020 14:00:35
User entered '98.3' F reason for change: Data Entry Error	Brad Killebrew (b) (4)	15 Sep 2020 14:00:35
User opened query 'per source temp is 98.3. Please review and update as needed. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 20:12:00 01 Sep 2020 20:08:20
User entered '97.8' F	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered 'Oral (Oral)'	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User closed query 'per source beats/min is 53 Please review and update as needed' (Site from CRA).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:56:32
DataPoint Verified.		17 Feb 2021 19:56:10
Query 'per source beats/min is 53 Please review and update as needed' answered with 'updated' (Site from CRA).	Brad Killebrew (b) (4)	15 Sep 2020 14:00:53
DataPoint Un-verified.	Brad Killebrew (b) (4)	15 Sep 2020 14:00:35
User entered '53' reason for change: Data Entry Error	Brad Killebrew (b) (4)	15 Sep 2020 14:00:35
User opened query 'per source beats/min is 53 Please review and update as needed' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 20:13:05
DataPoint Verified.		01 Sep 2020 20:08:20
User entered '56'	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'bpm'	System	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User closed query 'per source breaths/min is 14. Please review and update as needed' (Site from CRA).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:56:28
DataPoint Verified.		17 Feb 2021 19:56:10
Query 'per source breaths/min is 14. Please review and update as needed' answered with 'updated' (Site from CRA).	Brad Killebrew (b) (4)	15 Sep 2020 14:00:58
DataPoint Un-verified.	Brad Killebrew (b) (4)	15 Sep 2020 14:00:35
User entered '14' reason for change: Data Entry Error	Brad Killebrew (b) (4)	15 Sep 2020 14:00:35
User opened query 'per source breaths/min is 14. Please review and update as needed' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 20:13:34
DataPoint Verified.		01 Sep 2020 20:08:20
User entered '12'	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'breaths/min'	System	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User closed query 'per source is 129 . Please review and update as needed' (Site from CRA).	(b) (4)	17 Feb 2021 19:56:26
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:56:10
Query 'per source is 129 . Please review and update as needed' answered with 'updated' (Site from CRA).	Brad Killebrew (b) (4)	15 Sep 2020 14:01:03
DataPoint Un-verified.	Brad Killebrew (b) (4)	15 Sep 2020 14:00:35
User entered '129' reason for change: Data Entry Error	Brad Killebrew (b) (4)	15 Sep 2020 14:00:35
User opened query 'per source is 129 . Please review and update as needed' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 20:14:08
DataPoint Verified.		01 Sep 2020 20:08:20
User entered '147'	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'mmHg'	System	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User closed query 'per source is 68. Please review and update as needed' (Site from CRA).	(b) (4)	17 Feb 2021 19:56:22
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:56:10
Query 'per source is 68. Please review and update as needed' answered with 'updated' (Site from CRA).	Brad Killebrew (b) (4)	15 Sep 2020 14:01:08
DataPoint Un-verified.	(b) (4)	
	Brad Killebrew (b) (4)	15 Sep 2020 14:00:35
User entered '68' reason for change: Data Entry Error	Brad Killebrew (b) (4)	15 Sep 2020 14:00:35
User opened query 'per source is 68. Please review and update as needed' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 20:14:29
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered '83'	Leah Corts (b) (4)	25 Aug 2020 16:26:06
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:57:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'mmHg'	System	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User accepted default value 'Post-Dose (POSTDOSE)'	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered 'No (N)'	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:08:20
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:57:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	25 Aug 2020 16:26:06

US3122010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:57:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:15:13
User entered 'Yes (Y)'	Leah Corts (b) (4)	25 Aug 2020 16:26:22

US3122010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:57:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:15:13
User entered '25 Aug 2020'	Leah Corts (b) (4)	25 Aug 2020 16:26:22

US3122010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:15:21
User entered 'No (N)'	Leah Corts (b) (4)	25 Aug 2020 16:27:01

US3122010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:15:21
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	Leah Corts (b) (4)	25 Aug 2020 16:27:01

US3122010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:15:21
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:27:01

US3122010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	25 Aug 2020 16:27:01

US3122010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:15:21
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:27:01

US3122010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:15:21
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:27:01

US3122010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	25 Aug 2020 16:27:01

US3122010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:15:21
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:27:01

US3122010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 20:15:21
User entered empty.	System	25 Aug 2020 16:27:01

US3122010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:57:14

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	25 Aug 2020 16:27:01

US3122010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:55:05
User entered 'Yes (Y)'	Leah Corts (b) (4)	25 Aug 2020 16:27:18

US3122010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:55:05
User entered '25 Aug 2020'	Leah Corts (b) (4)	25 Aug 2020 16:27:18

US3122010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User closed query 'per source is time is 10:15am . Please review and update as needed ' (Site from CRA).	(b) (4), (b) (6)	21 Feb 2021 10:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:55:05
Query 'per source is time is 10:15am . Please review and update as needed ' answered with 'updated' (Site from CRA).	Brad Killebrew (b) (4)	15 Sep 2020 13:59:47
User entered '10:15' reason for change: Data Entry Error	Brad Killebrew (b) (4)	15 Sep 2020 13:59:40
User opened query 'per source is time is 10:15am . Please review and update as needed ' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 20:16:50
Query 'per source is time is 10:25am . Please review and update as needed' canceled (Site from CRA).		01 Sep 2020 20:16:41
User opened query 'per source is time is 10:25am . Please review and update as needed' (Site from CRA).		01 Sep 2020 20:16:19
User entered '11:29' reason for change: Data Entry Error	Leah Corts (b) (4)	25 Aug 2020 16:28:07
User entered '11:32'	Leah Corts (b) (4)	25 Aug 2020 16:27:18

US3122010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '25 Aug 2020 10:15'	System	15 Sep 2020 13:59:40
User entered '25 Aug 2020 11:29'	System	25 Aug 2020 16:28:07
User entered '25 Aug 2020 11:32'	System	25 Aug 2020 16:27:18

US3122010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 14:57:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:52:44
User entered '25 Aug 2020'	Leah Corts (b) (4)	25 Aug 2020 16:28:23

US3122010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:57:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Leah Corts (b) (4)	25 Aug 2020 16:28:23

US3122010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:57:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:52:44
User entered 'Yes (Y)'	Leah Corts (b) (4)	25 Aug 2020 16:28:23

US3122010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:57:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:52:44
User closed query 'per source is time is 10:25am . Please review and update as needed ' (Site from CRA).		17 Feb 2021 19:52:38
Query 'per source is time is 10:25am . Please review and update as needed ' answered with 'updated' (Site from CRA).	Brad Killebrew (b) (4)	15 Sep 2020 14:01:49
User entered '10:25' reason for change: Data Entry Error	Brad Killebrew (b) (4)	15 Sep 2020 14:01:43
User opened query 'per source is time is 10:25am . Please review and update as needed ' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 20:17:11
User entered '11:32'	Leah Corts (b) (4)	25 Aug 2020 16:28:23

US3122010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:57:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '25 Aug 2020 10:25'	System	15 Sep 2020 14:01:43
User entered '25 Aug 2020 11:32'	System	25 Aug 2020 16:28:23

US3122010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:57:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Leah Corts (b) (4)	25 Aug 2020 16:28:23

US3122010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:57:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:52:44
User entered 'No (N)'	Leah Corts (b) (4)	25 Aug 2020 16:28:23

US3122010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:57:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:52:44
User entered empty.	Leah Corts (b) (4)	25 Aug 2020 16:28:23

US3122010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:57:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	25 Aug 2020 16:28:23

US3122010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:17:37
User entered 'Yes (Y)'	Leah Corts (b) (4)	25 Aug 2020 16:28:34

US3122010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'I'	System	25 Aug 2020 16:28:34

US3122010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:06:14
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21SEP2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		24 Nov 2020 11:46:36
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21SEP2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'This information has been updated' (Site from DM).		09 Nov 2020 16:31:43
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21SEP2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		21 Oct 2020 08:00:46
User entered 'Yes (Y)'	Leah Corts (b) (4)	03 Sep 2020 17:55:54

US3122010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:06:14
User entered '02 Sep 2020'	Leah Corts (b) (4)	03 Sep 2020 17:55:54

US3122010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:06:14
User entered 'Contact Made (CONTACT MADE)'	Leah Corts (b) (4)	03 Sep 2020 17:55:54

US3122010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:06:14
User entered empty.	Leah Corts (b) (4)	03 Sep 2020 17:55:54

US3122010

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:06:18
User entered 'Yes (Y)'	Leah Corts (b) (4)	03 Sep 2020 17:56:02

US3122010

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'I'	System	03 Sep 2020 17:56:02

US3122010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:03:10
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	12 Mar 2021 17:28:52
Comment added 'Query opened to select on status but that has been done. Please close or advise on how to proceed.'	(b) (4), (b) (6)	12 Mar 2021 17:26:32
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	12 Mar 2021 17:25:17
Signature has been broken.	(b) (4), (b) (6)	12 Mar 2021 17:25:17
User entered 'No (N)' reason for change: Data Entry Error		12 Mar 2021 17:25:17
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
Query 'Per source, 2 Sep 2020 is the date of Safety Call Day 36, not Day 43. Please provide source for Safety Call Day 43. Otherwise clarify. ' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:26:52
User opened query 'Per source, 2 Sep 2020 is the date of Safety Call Day 36, not Day 43. Please provide source for Safety Call Day 43. Otherwise clarify. ' (Site from CRA).		10 Mar 2021 15:24:55
Query 'Please provide source for SDV.' canceled (Site from CRA).		10 Mar 2021 15:23:52
User opened query 'Please provide source for SDV.' (Site from CRA).		21 Jan 2021 17:09:34
User entered 'Yes (Y)'		09 Nov 2020 16:28:02

US3122010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:03:10
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
Signature has been broken.	(b) (4)	12 Mar 2021 17:25:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 17:25:17
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered '2 Sep 2020'	(b) (4)	09 Nov 2020 16:28:02
	(b) (4), (b) (6)	

US3122010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:03:10
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty; reason for change Data Entry Error	(b) (4)	(b) (4)
Signature has been broken.	(b) (4), (b) (6)	12 Mar 2021 17:28:52
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 17:25:17
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:25:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	12 Mar 2021 17:18:56
	(b) (4), (b) (6)	09 Nov 2020 16:28:02

US3122010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:03:10
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 17:25:17
User entered 'Recurrence of throat cancer & PCP requesting unblinding lead to safety call not being performed due to site waiting for guidance on the emergency unblinding. Guidance came after upper limit window.' reason for change: New Information		12 Mar 2021 17:25:17
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:28:02

US3122010

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:09:37
User entered 'Yes (Y)'		09 Nov 2020 16:28:08

US3122010

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'I'	System	09 Nov 2020 16:28:08

US3122010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:04:11
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:05:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:04:00

US3122010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:04:11
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:05:23
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:04:00

US3122010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:04:11
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:05:23
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:04:00

US3122010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:04:11
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:05:23
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:04:00

US3122010

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 15:28:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:29:53

US3122010

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'I'	System	09 Nov 2020 16:29:53

US3122010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:10:19
User entered 'Yes (Y)'		09 Nov 2020 16:30:11

US3122010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:10:19
User entered '21 Sep 2020'		09 Nov 2020 16:30:11

US3122010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[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 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:10:19
User entered 'Clinic (Clinic)'		09 Nov 2020 16:30:11

US3122010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'VISIT3'	System	09 Nov 2020 16:30:11

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:10:58
User entered 'No (N)'		09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (o) (4), (b) (6)	21 Jan 2021 17:10:58
User entered empty.		09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:10:58
User entered empty.		09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:10:58
User entered empty.		09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u), (4), (b) (6)	21 Jan 2021 17:10:58
User entered empty.		09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	21 Jan 2021 17:10:58
User entered empty.		09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	21 Jan 2021 17:10:58
User entered empty.		09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:10:58
User entered empty.		09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:10:58
User entered empty.		09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:10:58
User entered empty.		09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	09 Nov 2020 16:30:42

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:57:14

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:57:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:11:01
User entered 'No (N)'		09 Nov 2020 16:30:46

US3122010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:57:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:11:01
User entered empty.		09 Nov 2020 16:30:46

US3122010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	21 Jan 2021 17:11:53
User entered 'Yes (Y)'		09 Nov 2020 16:31:03

US3122010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:11:53
User entered '21 Sep 2020'		09 Nov 2020 16:31:03

US3122010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:11:53
User entered '10:49'		09 Nov 2020 16:31:03

US3122010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '21 Sep 2020 10:49'	System	09 Nov 2020 16:31:03

US3122010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:11:56
User entered 'Yes (Y)'		09 Nov 2020 16:31:07

US3122010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'I'	System	09 Nov 2020 16:31:07

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 64'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-09-26T00:01:49', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'd1a094dc-886d-4c40-86ed-7294d91374cf' User entered 'No (N)'	System	26 Sep 2020 04:02:49
	System	26 Sep 2020 04:02:49

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-09-26T00:02:12', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'd1a094dc-886d-4c40-86ed-7294d91374cf'	System	26 Sep 2020 04:02:49
User entered 'No (N)'	System	26 Sep 2020 04:02:49

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-09-26T00:02:24', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'd1a094dc-886d-4c40-86ed-7294d91374cf' User entered '26 Sep 2020 00:02:24'	System	26 Sep 2020 04:02:49
	System	26 Sep 2020 04:02:49

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '26 Sep 2020 00:01'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '30 Sep 2020 23:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 71'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-10-07T12:40:40', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '84c256bd-9119-415d-abea-2fb0d3d6c00e' User entered 'No (N)'	System	07 Oct 2020 16:40:58
	System	07 Oct 2020 16:40:58

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-10-07T12:40:48', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '84c256bd-9119-415d-abea-2fb0d3d6c00e'	System	07 Oct 2020 16:40:58
User entered 'No (N)'	System	07 Oct 2020 16:40:58

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-10-07T12:40:55', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '84c256bd-9119-415d-abea-2fb0d3d6c00e' User entered '07 Oct 2020 12:40:55'	System	07 Oct 2020 16:40:58
	System	07 Oct 2020 16:40:58

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '03 Oct 2020 00:01'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '07 Oct 2020 23:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 78'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-10-13T19:04:26', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '401f29ff-743f-44dd-b503-b06af1d7b032'	System	13 Oct 2020 23:04:47
User entered 'No (N)'	System	13 Oct 2020 23:04:47

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-10-13T19:04:33', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '401f29ff-743f-44dd-b503-b06af1d7b032'	System	13 Oct 2020 23:04:47
User entered 'No (N)'	System	13 Oct 2020 23:04:47

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-10-13T19:04:43', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '401f29ff-743f-44dd-b503-b06af1d7b032' User entered '13 Oct 2020 19:04:43'	System	13 Oct 2020 23:04:47
	System	13 Oct 2020 23:04:47

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '10 Oct 2020 00:01'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '14 Oct 2020 23:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 92'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-10-26T12:02:19', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '265dd7d6-3be8-43bb-8cb3-e67e2865ee71' User entered 'No (N)'	System	26 Oct 2020 16:04:21
	System	26 Oct 2020 16:04:21

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-10-26T12:02:24', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '265dd7d6-3be8-43bb-8cb3-e67e2865ee71'	System	26 Oct 2020 16:04:21
User entered 'No (N)'	System	26 Oct 2020 16:04:21

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-10-26T12:02:30', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '265dd7d6-3be8-43bb-8cb3-e67e2865ee71' User entered '26 Oct 2020 12:02:30'	System	26 Oct 2020 16:04:21
	System	26 Oct 2020 16:04:21

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '24 Oct 2020 00:01'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '28 Oct 2020 23:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 99'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-10-31T10:29:29', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'd2cafe84-ebe0-4c01-a71d-023c10bfe233'	System	31 Oct 2020 14:29:44
User entered 'No (N)'	System	31 Oct 2020 14:29:44

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-10-31T10:29:36', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'd2cafe84-ebe0-4c01-a71d-023c10bfe233'	System	31 Oct 2020 14:29:44
User entered 'No (N)'	System	31 Oct 2020 14:29:44

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-10-31T10:29:41', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'd2cafe84-ebe0-4c01-a71d-023c10bfe233' User entered '31 Oct 2020 10:29:41'	System	31 Oct 2020 14:29:44
	System	31 Oct 2020 14:29:44

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '31 Oct 2020 00:01'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '04 Nov 2020 23:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 106'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-11-07T18:42:57', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '0e48253b-3618-4461-b6f3-87031bf5643d' User entered 'No (N)'	System	07 Nov 2020 23:43:06
	System	07 Nov 2020 23:43:06

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-11-07T18:43:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '0e48253b-3618-4461-b6f3-87031bf5643d' User entered 'No (N)'	System	07 Nov 2020 23:43:06
	System	07 Nov 2020 23:43:06

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-11-07T18:43:03', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '0e48253b-3618-4461-b6f3-87031bf5643d' User entered '07 Nov 2020 18:43:03'	System	07 Nov 2020 23:43:06
	System	07 Nov 2020 23:43:06

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '07 Nov 2020 00:01'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '11 Nov 2020 23:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered 'Day 113'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-11-14T17:35:27', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'bed8b86f-f844-46c4-b835-fe3071eb5e74'	System	14 Nov 2020 22:35:46
User entered 'No (N)'	System	14 Nov 2020 22:35:46

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-11-14T17:35:35', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'bed8b86f-f844-46c4-b835-fe3071eb5e74'	System	14 Nov 2020 22:35:46
User entered 'No (N)'	System	14 Nov 2020 22:35:46

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-11-14T17:35:42', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'bed8b86f-f844-46c4-b835-fe3071eb5e74' User entered '14 Nov 2020 17:35:42'	System	14 Nov 2020 22:35:46
	System	14 Nov 2020 22:35:46

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '14 Nov 2020 00:01'	System	28 Jul 2020 19:39:27

US3122010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:34:27
Data entry locked.	System	28 Jul 2020 19:39:27
User entered '18 Nov 2020 23:59'	System	28 Jul 2020 19:39:27

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[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)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-11-25T12:53:05', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '109d6592-18d9-4037-87bd-6b28635b3dfc'	System	25 Nov 2020 17:53:18
User entered 'No (N)'	System	25 Nov 2020 17:53:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-11-25T12:53:12', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '109d6592-18d9-4037-87bd-6b28635b3dfc'	System	25 Nov 2020 17:53:18
User entered 'No (N)'	System	25 Nov 2020 17:53:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-11-25T12:53:16', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '109d6592-18d9-4037-87bd-6b28635b3dfc' User entered '25 Nov 2020 12:53:16'	System	25 Nov 2020 17:53:18
	System	25 Nov 2020 17:53:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-02T00:02:05', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'a0656758-0c96-4dd4-8676-a0b1d9fc44d6' User entered 'No (N)'	System	02 Dec 2020 05:02:22
	System	02 Dec 2020 05:02:22

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-02T00:02:11', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'a0656758-0c96-4dd4-8676-a0b1d9fc44d6'	System	02 Dec 2020 05:02:22
User entered 'No (N)'	System	02 Dec 2020 05:02:22

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-02T00:02:18', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'a0656758-0c96-4dd4-8676-a0b1d9fc44d6' User entered '02 Dec 2020 00:02:18'	System	02 Dec 2020 05:02:22
	System	02 Dec 2020 05:02:22

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-09T08:19:58', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '71922af9-9e23-43fb-b3f7-3bcd4e83fd8c'	System	09 Dec 2020 13:20:16
User entered 'No (N)'	System	09 Dec 2020 13:20:16

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-09T08:20:09', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '71922af9-9e23-43fb-b3f7-3bcd4e83fd8c'	System	09 Dec 2020 13:20:16
User entered 'No (N)'	System	09 Dec 2020 13:20:16

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-09T08:20:13', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '71922af9-9e23-43fb-b3f7-3bcd4e83fd8c' User entered '09 Dec 2020 08:20:13'	System	09 Dec 2020 13:20:16
	System	09 Dec 2020 13:20:16

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-16T00:01:29', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'c89097e8-4c74-4c7a-afe4-1212f6baf1a5' User entered 'No (N)'	System	16 Dec 2020 05:01:53
	System	16 Dec 2020 05:01:53

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-16T00:01:32', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'c89097e8-4c74-4c7a-afe4-1212f6baf1a5' User entered 'No (N)'	System	16 Dec 2020 05:01:53
	System	16 Dec 2020 05:01:53

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-16T00:01:36', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'c89097e8-4c74-4c7a-afe4-1212f6baf1a5' User entered '16 Dec 2020 00:01:36'	System	16 Dec 2020 05:01:53
	System	16 Dec 2020 05:01:53

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-23T07:48:21', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '5abca8d4-019f-4f3c-adea-dc3487d94e89'	System	23 Dec 2020 12:48:34
User entered 'No (N)'	System	23 Dec 2020 12:48:34

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-23T07:48:23', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '5abca8d4-019f-4f3c-adea-dc3487d94e89'	System	23 Dec 2020 12:48:34
User entered 'No (N)'	System	23 Dec 2020 12:48:34

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-23T07:48:28', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '5abca8d4-019f-4f3c-adea-dc3487d94e89' User entered '23 Dec 2020 07:48:28'	System	23 Dec 2020 12:48:34
	System	23 Dec 2020 12:48:34

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-30T07:44:54', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9728cf27-7a56-4587-8d4f-e99b467b43dc' User entered 'No (N)'	System	30 Dec 2020 12:45:19
	System	30 Dec 2020 12:45:19

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-30T07:45:06', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9728cf27-7a56-4587-8d4f-e99b467b43dc'	System	30 Dec 2020 12:45:19
User entered 'No (N)'	System	30 Dec 2020 12:45:19

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2020-12-30T07:45:14', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '9728cf27-7a56-4587-8d4f-e99b467b43dc' User entered '30 Dec 2020 07:45:14'	System	30 Dec 2020 12:45:19
	System	30 Dec 2020 12:45:19

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-06T14:05:21', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '10243e7b-93fa-4c5a-b0eb-467682ed1552'	System	06 Jan 2021 19:06:11
User entered 'Yes (Y)'	System	06 Jan 2021 19:06:11

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-06T14:05:29', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '10243e7b-93fa-4c5a-b0eb-467682ed1552'	System	06 Jan 2021 19:06:11
User entered 'No (N)'	System	06 Jan 2021 19:06:11

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[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)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-06T14:05:35', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '10243e7b-93fa-4c5a-b0eb-467682ed1552'	System	06 Jan 2021 19:06:11
User entered 'No (N)'	System	06 Jan 2021 19:06:11

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[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)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-06T14:05:42', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '10243e7b-93fa-4c5a-b0eb-467682ed1552'	System	06 Jan 2021 19:06:11
User entered 'Yes (Y)'	System	06 Jan 2021 19:06:11

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-06T14:05:51', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '10243e7b-93fa-4c5a-b0eb-467682ed1552'	System	06 Jan 2021 19:06:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 19:06:11

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-06T14:05:59', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '10243e7b-93fa-4c5a-b0eb-467682ed1552' User entered '06 Jan 2021 14:05:59'	System	06 Jan 2021 19:06:11
	System	06 Jan 2021 19:06:11

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-13T00:02:19', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '849ff403-7450-44eb-b879-c96aacfd5984'	System	13 Jan 2021 05:02:46
User entered 'No (N)'	System	13 Jan 2021 05:02:46

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-13T00:02:33', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '849ff403-7450-44eb-b879-c96aacfd5984'	System	13 Jan 2021 05:02:46
User entered 'No (N)'	System	13 Jan 2021 05:02:46

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-13T00:02:43', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '849ff403-7450-44eb-b879-c96aacfd5984' User entered '13 Jan 2021 00:02:43'	System	13 Jan 2021 05:02:46
	System	13 Jan 2021 05:02:46

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-20T08:23:50', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '066f72ea-eed6-4dcb-9d29-30fe3a9ff996'	System	20 Jan 2021 13:24:02
User entered 'No (N)'	System	20 Jan 2021 13:24:02

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-20T08:23:52', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '066f72ea-eed6-4dcb-9d29-30fe3a9ff996'	System	20 Jan 2021 13:24:02
User entered 'No (N)'	System	20 Jan 2021 13:24:02

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-20T08:23:59', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '066f72ea-eed6-4dcb-9d29-30fe3a9ff996' User entered '20 Jan 2021 08:23:59'	System	20 Jan 2021 13:24:02
	System	20 Jan 2021 13:24:02

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-27T00:05:37', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '2d12231d-5701-4ccc-a22e-9a60a7c70536'	System	27 Jan 2021 05:05:47
User entered 'No (N)'	System	27 Jan 2021 05:05:47

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-27T00:05:38', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '2d12231d-5701-4ccc-a22e-9a60a7c70536'	System	27 Jan 2021 05:05:47
User entered 'No (N)'	System	27 Jan 2021 05:05:47

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-01-27T00:05:42', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '2d12231d-5701-4ccc-a22e-9a60a7c70536' User entered '27 Jan 2021 00:05:42'	System	27 Jan 2021 05:05:47
	System	27 Jan 2021 05:05:47

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-02-05T12:01:14', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'c22efc02-96cd-4ca2-a498-491a08518bd3' User entered 'No (N)'	System	05 Feb 2021 17:04:53
	System	05 Feb 2021 17:04:53

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-02-05T12:01:16', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'c22efc02-96cd-4ca2-a498-491a08518bd3'	System	05 Feb 2021 17:04:53
User entered 'No (N)'	System	05 Feb 2021 17:04:53

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-02-05T12:01:24', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'c22efc02-96cd-4ca2-a498-491a08518bd3' User entered '05 Feb 2021 12:01:24'	System	05 Feb 2021 17:04:53
	System	05 Feb 2021 17:04:53

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-02-10T00:01:29', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '6abe3d3d-3a66-4270-a286-0a3ac7a0c7d3' User entered 'No (N)'	System	10 Feb 2021 05:02:28
	System	10 Feb 2021 05:02:28

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-02-10T00:01:32', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '6abe3d3d-3a66-4270-a286-0a3ac7a0c7d3'	System	10 Feb 2021 05:02:28
User entered 'No (N)'	System	10 Feb 2021 05:02:28

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-02-10T00:01:36', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: '6abe3d3d-3a66-4270-a286-0a3ac7a0c7d3' User entered '10 Feb 2021 00:01:36'	System	10 Feb 2021 05:02:28
	System	10 Feb 2021 05:02:28

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-02-21T13:04:26', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'e78376c0-f5a7-4bdd-9dd0-a368c8f67a85'	System	21 Feb 2021 18:07:42
User entered 'No (N)'	System	21 Feb 2021 18:07:42

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-02-21T13:04:29', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'e78376c0-f5a7-4bdd-9dd0-a368c8f67a85'	System	21 Feb 2021 18:07:42
User entered 'No (N)'	System	21 Feb 2021 18:07:42

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-02-21T13:04:33', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'e78376c0-f5a7-4bdd-9dd0-a368c8f67a85' User entered '21 Feb 2021 13:04:33'	System	21 Feb 2021 18:07:42
	System	21 Feb 2021 18:07:42

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-02-26T12:00:22-05:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b704de4b-a1d4-4e67-82c1-a5f2a610c345'	System	26 Feb 2021 17:01:24
User entered 'No (N)'	System	26 Feb 2021 17:01:24

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-02-26T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b704de4b-a1d4-4e67-82c1-a5f2a610c345'	System	26 Feb 2021 17:01:24
User entered 'No (N)'	System	26 Feb 2021 17:01:24

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-02-26T12:00:30-05:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'b704de4b-a1d4-4e67-82c1-a5f2a610c345'	System	26 Feb 2021 17:01:24
User entered '26 Feb 2021 17:00:30'	System	26 Feb 2021 17:01:24

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-03-03T18:26:18-05:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'fe0fba78-c11c-4bd3-8998-3892ae835340' User entered 'No (N)'	System	03 Mar 2021 23:26:29
	System	03 Mar 2021 23:26:29

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-03-03T18:26:22-05:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'fe0fba78-c11c-4bd3-8998-3892ae835340'	System	03 Mar 2021 23:26:29
User entered 'No (N)'	System	03 Mar 2021 23:26:29

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-03-03T18:26:26-05:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'fe0fba78-c11c-4bd3-8998-3892ae835340' User entered '03 Mar 2021 18:26:26'	System	03 Mar 2021 23:26:29
	System	03 Mar 2021 23:26:29

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-03-12T11:31:36-05:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'a0d5541e-efaa-4c69-99be-2741aed501de' User entered 'No (N)'	System	12 Mar 2021 16:31:44
	System	12 Mar 2021 16:31:44

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-03-12T11:31:38-05:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'a0d5541e-efaa-4c69-99be-2741aed501de'	System	12 Mar 2021 16:31:44
User entered 'No (N)'	System	12 Mar 2021 16:31:44

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-03-12T11:31:41-05:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'a0d5541e-efaa-4c69-99be-2741aed501de' User entered '12 Mar 2021 11:31:41'	System	12 Mar 2021 16:31:44
	System	12 Mar 2021 16:31:44

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:02:18

US3122010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:57:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:02:18
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:02:18

US3122010

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Jun 2021 14:57:14

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)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-03-03T18:26:44-05:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'cee088bd-ed9d-4e5b-baa3-7d9bdc947540' User entered 'No (N)'	System	03 Mar 2021 23:26:56
	System	03 Mar 2021 23:26:56

US3122010

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Jun 2021 14:57:14

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7527D21B-409A-48EB-A436-817A828F1190)', Time: '2021-03-03T18:26:52-05:00', User OID: 'PatientReportedOutcome (US3122010)', ODM File OID: 'cee088bd-ed9d-4e5b-baa3-7d9bdc947540' User entered '03 Mar 2021 18:26:52'	System	03 Mar 2021 23:26:56
	System	03 Mar 2021 23:26:56

US3122010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:04:36
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:29:05

US3122010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:04:36
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:29:05

US3122010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:04:36
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:29:05

US3122010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:57:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:04:36
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:29:05

US3122010

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:04:52
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:29:14

US3122010

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:57:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 17:29:14

US3122010

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Jun 2021 14:57:14

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:32:05
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:29:29

US3122010

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

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:06:20
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:33:50

US3122010

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

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:06:20
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:33:50

US3122010

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

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[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 03:45:07
DataPoint Verified.		06 Apr 2021 15:06:20
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:33:50

US3122010

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

Form: Visit Date

Generated On: 11 Jun 2021 14:57:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'UNBLND_DECIDE'	System	12 Mar 2021 17:33:50

US3122010

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

Form: Unblinding

Generated On: 11 Jun 2021 14:57:14

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User closed query 'Per Sponsor: 'NA unblinded under A5 and study discon is ticked' but 'Protocol version for participant unblinding is A6 or later or blank' please reconcile' (Site from DM).		15 Apr 2021 01:20:33
Query 'Per Sponsor: 'NA unblinded under A5 and study discon is ticked' but 'Protocol version for participant unblinding is A6 or later or blank' please reconcile' answered with 'This is a duplicate query. Kindly please remove' (Site from DM).		09 Apr 2021 13:41:28
User opened query 'Per Sponsor: 'NA unblinded under A5 and study discon is ticked' but 'Protocol version for participant unblinding is A6 or later or blank' please reconcile' (Site from DM).		07 Apr 2021 22:47:46
DataPoint Verified.		06 Apr 2021 15:31:02
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 17:34:04

US3122010

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

Form: Unblinding

Generated On: 11 Jun 2021 14:57:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:31:02
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered '1' reason for change: Data Entry Error	(b) (4)	12 Mar 2021 17:36:28
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 17:34:04

US3122010

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

Form: Unblinding

Generated On: 11 Jun 2021 14:57:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:31:02
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).		15 Mar 2021 06:09:24
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'updated' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:36:44
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	12 Mar 2021 17:36:37
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 17:36:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Mar 2021 17:36:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 17:36:37
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 17:36:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 17:36:28
User entered 'No (N)'		12 Mar 2021 17:34:04

US3122010

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

Form: Unblinding

Generated On: 11 Jun 2021 14:57:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	15 Apr 2021 19:15:38
User closed query 'Sponsor Review: Per IRT subject was unblinded under A5 but unblinding form states 'unblinded under A6 or later' or is blank. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	15 Apr 2021 01:20:04
DataPoint Verified.		13 Apr 2021 14:36:38
Query 'Sponsor Review: Per IRT subject was unblinded under A5 but unblinding form states 'unblinded under A6 or later' or is blank. ' answered with 'updated' (Site from DM).		09 Apr 2021 13:41:30
DataPoint Un-verified.		09 Apr 2021 13:40:35
Signature has been broken.		09 Apr 2021 13:40:35
User entered 'Amendment 5 (Amendment 5)' reason for change: Data Entry Error		09 Apr 2021 13:40:35
User opened query 'Sponsor Review: Per IRT subject was unblinded under A5 but unblinding form states 'unblinded under A6 or later' or is blank. ' (Site from DM).		07 Apr 2021 19:18:51
DataPoint Verified.		06 Apr 2021 15:31:02
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:34:04

US3122010

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

Form: Unblinding

Generated On: 11 Jun 2021 14:57:14

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	15 Apr 2021 19:15:38
User closed query 'Per IRT, subject was unblinded on 14SEP2020. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 01:18:28
DataPoint Verified.		13 Apr 2021 14:36:42
Query 'Per IRT, subject was unblinded on 14SEP2020. Please review and reconcile.' answered with 'updated' (Site from DM).		09 Apr 2021 13:40:43
DataPoint Un-verified.		09 Apr 2021 13:40:35
Signature has been broken.		09 Apr 2021 13:40:35
User entered '14 Sep 2020' reason for change: Data Entry Error		09 Apr 2021 13:40:35
User opened query 'Per IRT, subject was unblinded on 14SEP2020. Please review and reconcile.' (Site from DM).		08 Apr 2021 16:44:42
DataPoint Verified.		06 Apr 2021 15:31:02
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 20:40:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:04:17
User entered '24 Sep 2020' reason for change: Data Entry Error		30 Mar 2021 15:04:17
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:34:04

US3122010

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

Form: Unblinding

Generated On: 11 Jun 2021 14:57:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:31:02
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 20:40:31
Signature has been broken.	(b) (4)	30 Mar 2021 15:04:17
User entered 'mRNA-1273 (mRNA-1273)' reason	(b) (4), (b) (6)	30 Mar 2021 15:04:17
for change: Data Entry Error		
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4)	12 Mar 2021 17:34:04
	(b) (4), (b) (6)	

US3122010

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

Form: Unblinding

Generated On: 11 Jun 2021 14:57:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:31:02
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 20:40:31
Signature has been broken.	(b) (4)	30 Mar 2021 15:04:17
User entered 'mRNA-1273 (mRNA-1273)' reason	(b) (4), (b) (6)	30 Mar 2021 15:04:17
for change: Data Entry Error		
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4)	12 Mar 2021 17:34:04
	(b) (4), (b) (6)	

US3122010

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

Form: Unblinding

Generated On: 11 Jun 2021 14:57:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:31:02
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 20:40:31
Signature has been broken.	(b) (4)	30 Mar 2021 15:04:17
User entered 'Not Administered (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 15:04:17
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4)	12 Mar 2021 17:34:04
	(b) (4), (b) (6)	

US3122010

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

Form: Unblinding

Generated On: 11 Jun 2021 14:57:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:31:02
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 20:40:31
Signature has been broken.	(b) (4)	30 Mar 2021 15:04:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 15:04:17
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:34:04

US3122010

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

Form: Unblinding

Generated On: 11 Jun 2021 14:57:14

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 17:34:04

US3122010

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

Form: Unblinding

Generated On: 11 Jun 2021 14:57:14

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 17:34:04

US3122010

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:31:18
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:36:54

US3122010

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:31:18
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:36:54

US3122010

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:31:18
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:36:54

US3122010

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:57:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 17:36:54

US3122010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 14:57:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:31:20
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:36:57

US3122010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:31:20
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:36:57

US3122010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 14:57:14

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 15:31:20
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:36:57

US3122010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 14:57:14

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 17:36:57

US3122010

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Jun 2021 14:57:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:54:42
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE PAIN persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:40:24
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE PAIN persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'UPDATED' (Site from DM).		12 Mar 2021 17:52:10
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE PAIN persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).		09 Feb 2021 01:37:16
DataPoint Verified.		01 Sep 2020 20:32:46
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	18 Aug 2020 20:26:30

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	2 Oct 2020 20:25:44
Reviewed for Safety.		9 Aug 2020 17:08:10
User entered 'USA-US063-2020-mRNA-1273-P301000001'	System	19 Aug 2020 17:07:59
User entered 'New'	(b) (4), (b) (6)	19 Aug 2020 17:07:59

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 16:20:09
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Respiratory tract and pleural neoplasms malignant cell type unspecified NEC, PT: Throat cancer, LLT: Throat cancer - version MedDRA\23.0.	Coder Import (b) (4)	16 Mar 2021 16:44:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Mar 2021 16:44:53
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
Data point term sent to Coder	System (b) (4)	12 Mar 2021 16:19:30
User entered 'RECURRENCE OF THROAT CANCER [WITH METASTASES TO LUNGS]'	(b) (4), (b) (6)	12 Mar 2021 16:18:44
reason for change: Data Entry Error		
Data point term sent to Coder	System	12 Mar 2021 16:18:29
Data point term sent to Coder	System	12 Mar 2021 16:18:28
User closed query 'For coding purposes, please split RECURRENCE OF THROAT CANCER WITH METASTASES TO LUNGS into separate entries. 1. RECURRENCE OF THROAT CANCER [WITH METASTASES TO LUNGS] and 2. [RECURRENCE OF THROAT CANCE] WITH METASTASES TO LUNGS' (Site from System).	System	12 Mar 2021 16:18:28
Query 'For coding purposes, please split RECURRENCE OF THROAT CANCER WITH METASTASES TO LUNGS into separate entries. 1. RECURRENCE OF THROAT CANCER [WITH METASTASES TO LUNGS] and 2. [RECURRENCE OF THROAT CANCE] WITH METASTASES TO LUNGS' answered with 'updated' (Site from System).		
User entered 'RECURRENCE OF THROAT CANCER [WITH METASTASES TO LUNGS]up'		12 Mar 2021 16:18:17
reason for change: Data Entry Error		
DataPoint Un-verified.		12 Mar 2021 16:17:52
Coding entries removed.		12 Mar 2021 16:17:52

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'RECURRENCE OF THROAT CANCER [WITH METASTASES TO LUNGS]'	(b) (4), (b) (6)	12 Mar 2021 16:17:52
reason for change: Data Entry Error		
User opened query 'For coding purposes, please split RECURRENCE OF THROAT CANCER WITH METASTASES TO LUNGS into separate entries. 1. RECURRENCE OF THROAT CANCER [WITH METASTASES TO LUNGS] and 2. [RECURRENCE OF THROAT CANCER] WITH METASTASES TO LUNGS' (Site from System). DataPoint Verified.	Coder Import (b) (4) (b) (4)	12 Mar 2021 14:24:45
	(b) (4), (b) (6)	02 Oct 2020 20:25:44
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Respiratory tract and pleural neoplasms malignant cell type unspecified NEC, PT: Lung cancer metastatic, LLT: Lung cancer metastatic - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 12:56:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 12:56:46
User closed query 'PV Query: It was reported that the CT revealed recurrence of cancer with metastases to the lung, however the event term reports a diagnosis of lung cancer. Please confirm if the patient had a recurrence of throat cancer with metastases, or a new primary lung cancer, and consider updating event term as necessary to most accurately reflect the diagnosis.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 19:15:51
Data point term sent to Coder	System	25 Aug 2020 18:20:39
Query 'PV Query: It was reported that the CT revealed recurrence of cancer with metastases to the lung, however the event term reports a diagnosis of lung cancer. Please confirm if the patient had a recurrence of throat cancer with metastases, or a new primary lung cancer, and consider updating event term as necessary to most accurately reflect the diagnosis.' answered with 'updated to clarify' (Site from Safety).	Brad Killebrew (b) (4)	25 Aug 2020 18:20:02
Coding entries removed.	Brad Killebrew (b) (4)	25 Aug 2020 18:19:51

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Recurrence of throat cancer with metastases to lungs' reason for change: Data Entry Error	Brad Killebrew (b) (4)	25 Aug 2020 18:19:51
User opened query 'PV Query: It was reported that the CT revealed recurrence of cancer with metastases to the lung, however the event term reports a diagnosis of lung cancer. Please confirm if the patient had a recurrence of throat cancer with metastases, or a new primary lung cancer, and consider updating event term as necessary to most accurately reflect the diagnosis.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:30:11
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Respiratory tract and pleural neoplasms malignant cell type unspecified NEC, PT: Lung carcinoma cell type unspecified stage IV, LLT: Lung cancer stage IV - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:42:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:42:19
Data point term sent to Coder	System	18 Aug 2020 20:31:18
User entered 'Stage 4 Cancer - Lungs'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User closed query 'Per MM: Please confirm if this was not a medically attended adverse event.' (Site from DM).	(b) (4) (u) (4), (b) (6)	08 Oct 2020 08:38:33
DataPoint Verified.		02 Oct 2020 20:25:44
Query 'Per MM: Please confirm if this was not a medically attended adverse event.' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	01 Oct 2020 15:49:44
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 15:49:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 15:49:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Brad Killebrew (b) (4)	01 Oct 2020 15:49:32
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:25:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:25:12
User opened query 'Per MM: Please confirm if this was not a medically attended adverse event.' (Site from DM).		03 Sep 2020 17:01:17
User entered 'No (N)'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered 'No (N)'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 18:20:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 18:20:13
User entered 'No (N)' reason for change: Data Entry Error	Brad Killebrew (b) (4)	25 Aug 2020 18:20:13
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 13:32:09
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 13:32:09
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:01

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered '12 Aug 2020'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
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	18 Aug 2020 20:31:47
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	18 Aug 2020 20:31:47
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	18 Aug 2020 20:31:08
User entered '00:00'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	18 Aug 2020 20:31:47
User entered '12 Aug 2020 00:00'	System	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 13:29:02
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		30 Nov 2020 13:28:05
DataPoint Verified.		02 Oct 2020 20:25:44
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		01 Oct 2020 17:40:58
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'data pending' (Site from Safety).	Brad Killebrew (b) (4)	01 Oct 2020 15:49:56
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:26:52
User entered empty.	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered empty.	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).		30 Nov 2020 13:28:00
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		02 Oct 2020 17:23:02
User entered empty.	System	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered 'Grade 3/Severe (Grade 3/Severe)'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered '0'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered '0'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered '0'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered empty.	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered empty.	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered empty.	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered empty.	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered '0'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered '0'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered 'l'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).		25 Sep 2020 02:11:28
Comment added 'Data correct. SAE is not related but serious enough to warrant termination of study procedure.'	Leah Corts (b) (4)	20 Aug 2020 15:50:49
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	18 Aug 2020 20:31:08
User entered 'Not Related (NOT RELATED)'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered 'Not Related (NOT RELATED)'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User closed query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:16:31
Query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' answered with 'This is reflected' (Site from DM).		10 Nov 2020 21:10:02
User opened query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).		26 Oct 2020 09:59:33
User closed query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you.' (Site from DM).		07 Oct 2020 16:44:26
DataPoint Verified.		02 Oct 2020 20:25:44
Query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you.' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	01 Oct 2020 15:51:21
User opened query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 03:15:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	0 Mar 2021 15:38:45
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).		6 Feb 2021 16:10:07
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. '	Leah Corts (b) (4)	12 Feb 2021 16:22:47
answered with 'corrected' (Site from DM).		
DataPoint Un-verified.	Leah Corts (b) (4)	12 Feb 2021 16:16:34
User entered '0' reason for change: Data Entry Error	Leah Corts (b) (4)	12 Feb 2021 16:16:34
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc 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)	08 Jan 2021 00:20:27
DataPoint Verified.		02 Oct 2020 20:25:44
User entered '1'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 16:20:42
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Un-verified.	(b) (4)	12 Mar 2021 16:45:24
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 16:45:24
DataPoint Verified.		02 Oct 2020 20:25:44
User entered '0'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 16:20:46
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:16:51
User closed query 'Per DM CLR - RQ: Response noted. However, please tick this field if therapeutic surgery/procedure is given. Either update this field or update Con Proc eCRF to include a therapeutic procedure. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:58:37
Query 'Per DM CLR - RQ: Response noted. However, please tick this field if therapeutic surgery/procedure is given. Either update this field or update Con Proc eCRF to include a therapeutic procedure. ' answered with 'I have removed the check. ' (Site from DM).		22 Mar 2021 19:10:52
DataPoint Un-verified.		22 Mar 2021 19:10:19
Signature has been broken.		22 Mar 2021 19:10:19
User entered '0' reason for change: Data Entry Error		22 Mar 2021 19:10:19
User opened query 'Per DM CLR - RQ: Response noted. However, please tick this field if therapeutic surgery/procedure is given. Either update this field or update Con Proc eCRF to include a therapeutic procedure. ' (Site from DM).		21 Mar 2021 05:11:40
User closed query 'Per DM CLR: Other Action Take = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).		15 Mar 2021 14:41:21
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	12 Mar 2021 17:18:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' answered with 'updated.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:46:03
		10 Mar 2021 15:44:35
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM). DataPoint Un-verified.		02 Mar 2021 18:21:26
	Leah Corts (b) (4)	12 Feb 2021 16:16:34
User entered '1' reason for change: Data Entry Error	Leah Corts (b) (4)	12 Feb 2021 16:16:34
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered '0'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:39:10
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Condition not expected to resolve' (Site from Safety).	Leah Corts (b) (4)	22 Oct 2020 18:16:41
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 20:25:44
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		02 Oct 2020 17:23:25
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		01 Oct 2020 17:41:02
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'data is pending' (Site from Safety).	Brad Killebrew (b) (4)	01 Oct 2020 15:51:38
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:31:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 20:31:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Brad Killebrew (b) (4)	18 Aug 2020 20:31:47
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:31:08
User entered empty.	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:25:44
User entered empty.	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WITH A HISTORY OF THROAT CANCER WAS CALLED ON 18AUG2020 FOR SAFETY CALL #3. SUBJECT REPORTED THAT DURING A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED AND HAS SPREAD TO THEIR LUNGS. PATIENT IS SCHEDULED FOR ONCOLOGY FOLLOW-UP ON 02SEP2020. MORE DETAILS, INCLUDING TREATMENT/PROCEDURES WILL BE REPORTED AS THE DATA BECOMES AVAILABLE. 9/24/2020 VISIT INFORMATION (ADDED FROM MEDICAL RECORDS RECEIVED 09OCT2020) DIAGNOSIS: SUBJECT IS DIAGNOSED WITH SQUAMOUS CELL CARCINOMA - LEFT TONSIL. STAGE: T2N2 (AJCC 8TH EDITION) T2N2C (7TH EDITION) MOLECULAR: P16+ GENE VARIANCE OF UNCERTAIN SIGNIFICANCE: CTNNB1: C.97T>A [P.SER33THR] CPS 2 ON CYCLE 1 OF PEMBROLIZUMAB. PLAN(DOCTOR'S NOTES): #SCC - LEFT TONSIL, T2N2 -NOW WITH BIOPSY PROVEN RECURRENT/METASTATIC DISEASE IN THE LUNGS -GIVEN LOW BURDEN, ASYMPTOMATIC DISEASE AND PD-L1 CPS 2, WILL PROCEED WITH FRONT LINE PEMBROLIZUMAB PER KN048. [CYCLE ONE STARTED SAME DAY AS NOTES]' (WR#5445128)	System	11 Jun 2021 14:45:08
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 16:21:13
User closed query 'Per CDM: Please leave the query open until the data is received. Thank You.' (Site from DM).		22 Mar 2021 12:36:04
User signature succeeded.	Matthew Hong (b) (4)	17 Mar 2021 14:58:22
Query 'Per CDM: Please leave the query open until the data is received. Thank You.' answered with '~The information was already added to the con meds' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 12:48:28

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified. Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 12:48:22
User entered 'SUBJECT WITH A HISTORY OF THROAT CANCER WAS CALLED ON 18AUG2020 FOR SAFETY CALL #3. SUBJECT REPORTED THAT DURING A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED AND HAS SPREAD TO THEIR LUNGS. PATIENT IS SCHEDULED FOR ONCOLOGY FOLLOW-UP ON 02SEP2020. MORE DETAILS, INCLUDING TREATMENT/PROCEDURES WILL BE REPORTED AS THE DATA BECOMES AVAILABLE.		17 Mar 2021 12:48:22
9/24/2020 VISIT INFORMATION (ADDED FROM MEDICAL RECORDS RECEIVED 09OCT2020) DIAGNOSIS: SUBJECT IS DIAGNOSED WITH SQUAMOUS CELL CARCINOMA - LEFT TONSIL. STAGE: T2N2 (AJCC 8TH EDITION) T2N2C (7TH EDITION) MOLECULAR: P16+ GENE VARIANCE OF UNCERTAIN SIGNIFICANCE: CTNNB1: C.97T>A [P.SER33THR] CPS 2 ON CYCLE 1 OF PEMBROLIZUMAB. PLAN(DOCTOR'S NOTES): #SCC - LEFT TONSIL, T2N2 -NOW WITH BIOPSY PROVEN RECURRENT/METASTATIC DISEASE IN THE LUNGS -GIVEN LOW BURDEN, ASYMPTOMATIC DISEASE AND PD-L1 CPS 2, WILL PROCEED WITH FRONT LINE PEMBROLIZUMAB PER KN048. [Cycle one started same day as notes]' reason for change: New Information		
User opened query 'Per CDM: Please leave the query open until the data is received. Thank You.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 14:59:42

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = WILL PROCEED WITH FRONT LINE PEMBROLIZUMAB PER KN048. However, please confirm if this was already started. If yes, please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Mar 2021 14:59:42
Comment added 'PEMBROLIZUMAB information has been added to con meds'. Query 'Per DM CLR: SAE Narrative = WILL PROCEED WITH FRONT LINE PEMBROLIZUMAB PER KN048. However, please confirm if this was already started. If yes, please review and ensure that this is captured in the appropriate eCRF. ' answered with 'According to the document this information was taken from, they were starting it that week and would return within 2 weeks for second cycle. Clarification on treatment information was requested but has not been received. Previous request for information has been sent to doctor but nothing has been sent back.' (Site from DM).	Matthew Hong (b) (4) (b) (4) (b) (4), (b) (6)	12 Mar 2021 17:18:56 12 Mar 2021 16:54:37 12 Mar 2021 16:31:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:50:04
User closed query 'Per DM CLR: SAE Narrative = A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED. However, ConProc indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).		16 Feb 2021 16:11:30
Query 'Per DM CLR: SAE Narrative = A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED. However, ConProc indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' answered with 'Corrected' (Site from DM).	Leah Corts (b) (4)	15 Feb 2021 13:54:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = WILL PROCEED WITH FRONT LINE PEMBROLIZUMAB PER KN048. However, please confirm if this was already started. If yes, please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 00:20:52
User opened query 'Per DM CLR: SAE Narrative = A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED. However, ConProc indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).		08 Jan 2021 00:20:46
User closed query 'PV Query: Please provide copy of consultation note from oncology appointment. ' (Site from Safety).		30 Nov 2020 20:03:54
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (CT scan and any further imaging). Please include dates, units and reference ranges if applicable. ' (Site from Safety).		30 Nov 2020 20:03:50
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		30 Nov 2020 20:03:43
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated information from 24Sep2020 doctor visit.' (Site from Safety).		25 Nov 2020 18:20:49
DataPoint Un-verified.		25 Nov 2020 18:19:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WITH A HISTORY OF THROAT CANCER WAS CALLED ON 18AUG2020 FOR SAFETY CALL #3. SUBJECT REPORTED THAT DURING A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED AND HAS SPREAD TO THEIR LUNGS. PATIENT IS SCHEDULED FOR ONCOLOGY FOLLOW-UP ON 02SEP2020. MORE DETAILS, INCLUDING TREATMENT/PROCEDURES WILL BE REPORTED AS THE DATA BECOMES AVAILABLE. 9/24/2020 Visit Information (added from medical records received 09OCT2020) Diagnosis: Subject is diagnosed with squamous cell carcinoma - left tonsil. Stage: t2n2 (AJCC 8th edition) T2N2c (7th edition) Molecular: p16+ Gene variance of uncertain significance: CTNNB1: c.97t>A [p.Ser33Thr] CPS 2 On cycle 1 of Pembrolizumab. Plan(Doctor's notes): #scc - left tonsil, T2N2 -Now with biopsy proven recurrent/metastatic disease in the lungs -given low burden, asymptomatic disease and PD-L1 CPS 2, will proceed with front line pembrolizumab per KN048 ' reason for change: New Information	(b) (4), (b) (6)	25 Nov 2020 18:19:52
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (CT scan and any further imaging). Please include dates, units and reference ranges if applicable. ' answered with 'Added to source binder' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:26:55
Query 'PV Query: Please provide copy of consultation note from oncology appointment. ' answered with 'Added to source binder' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:26:37
User closed query 'PV query: Please provide histology grade/stage of throat cancer, if available. ' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:08:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = SUBJECT REPORTED THAT DURING A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED AND HAS SPREAD TO THEIR LUNGS. However, this is not captured in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 11:31:49
Query 'PV query: Please provide histology grade/stage of throat cancer, if available. ' answered with 'Grade 3' (Site from Safety).		20 Nov 2020 22:15:27
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		20 Nov 2020 15:18:47
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (CT scan and any further imaging). Please include dates, units and reference ranges if applicable. ' (Site from Safety).		20 Nov 2020 15:18:37
User opened query 'PV Query: Please provide copy of consultation note from oncology appointment. ' (Site from Safety).		20 Nov 2020 15:18:25
User opened query 'PV query: Please provide histology grade/stage of throat cancer, if available. ' (Site from Safety).		20 Nov 2020 15:18:13
Query 'Per DM CLR: SAE Narrative = SUBJECT REPORTED THAT DURING A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED AND HAS SPREAD TO THEIR LUNGS. However, this is not captured in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'The Catscan is listed in the ConPro area. Please advise on what else needs to be done to close out this Query ' (Site from DM).		19 Nov 2020 17:08:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide histology grade/stage of throat cancer, if available.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:08:20
User closed query 'PV Query: Please provide copy of consultation note from oncology appointment.' (Site from Safety).		11 Nov 2020 21:07:50
User closed query 'PV Query: Please report if the patient had any risk factors, other than prior throat cancer (ie. smoking, family history, etc.).' (Site from Safety).		11 Nov 2020 21:07:46
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		11 Nov 2020 21:07:43
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (CT scan and any further imaging). Please include dates, units and reference ranges if applicable.' (Site from Safety).		11 Nov 2020 21:07:40
Query 'PV query: Please provide histology grade/stage of throat cancer, if available.' answered with 'Requested information from Oncologist on 9/29. Have not received information yet. Sending follow up request today 11/10/2020' (Site from Safety).		10 Nov 2020 21:05:41
Query 'PV Query: Please report if the patient had any risk factors, other than prior throat cancer (ie. smoking, family history, etc.).' answered with 'No risk factors' (Site from Safety).		10 Nov 2020 21:05:34
Query 'PV Query: Please provide copy of consultation note from oncology appointment.' answered with 'Requested information from Oncologist on 9/29. Have not received information yet. Sending follow up request today 11/10/2020' (Site from Safety).		10 Nov 2020 21:05:21

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Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Requested information from Oncologist on 9/29. Have not received information yet. Sending follow up request today 11/10/2020' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:05:18
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (CT scan and any further imaging). Please include dates, units and reference ranges if applicable.' answered with 'Requested information from Oncologist on 9/29. Have not received information yet. Sending follow up request today 11/10/2020' (Site from Safety).		10 Nov 2020 21:05:15
User opened query 'Per DM CLR: SAE Narrative = SUBJECT REPORTED THAT DURING A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED AND HAS SPREAD TO THEIR LUNGS. However, this is not captured in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		13 Oct 2020 01:26:38
DataPoint Verified.		02 Oct 2020 20:25:44
User opened query 'PV query: Please provide histology grade/stage of throat cancer, if available.' (Site from Safety).		02 Oct 2020 17:24:26
User opened query 'PV Query: Please report if the patient had any risk factors, other than prior throat cancer (ie. smoking, family history, etc.).' (Site from Safety).		02 Oct 2020 17:24:02
User opened query 'PV Query: Please provide copy of consultation note from oncology appointment.' (Site from Safety).		02 Oct 2020 17:23:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:23:43
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (CT scan and any further imaging). Please include dates, units and reference ranges if applicable.' (Site from Safety).		02 Oct 2020 17:23:34
User closed query 'PV Query: Please provide histology grade/stage of throat cancer, if available.' (Site from Safety).		01 Oct 2020 17:41:13
User closed query 'PV Query: Please report if the patient had any risk factors, other than prior throat cancer (ie. smoking, family history, etc.).' (Site from Safety).		01 Oct 2020 17:41:11
User closed query 'PV Query: Please provide copy of consultation note from oncology appointment.' (Site from Safety).		01 Oct 2020 17:41:10
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		01 Oct 2020 17:41:07
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (CT scan and any further imaging). Please include dates, units and reference ranges if applicable.' (Site from Safety).		01 Oct 2020 17:41:05
Query 'PV Query: Please provide histology grade/stage of throat cancer, if available.' answered with 'records have been requested, data is pending' (Site from Safety).	Brad Killebrew (b) (4)	01 Oct 2020 15:52:21

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please report if the patient had any risk factors, other than prior throat cancer (ie. smoking, family history, etc.).' answered with 'records have been requested, data is pending' (Site from Safety).	Brad Killebrew (b) (4)	01 Oct 2020 15:52:17
Query 'PV Query: Please provide copy of consultation note from oncology appointment.' answered with 'records have been requested, data is pending' (Site from Safety).	Brad Killebrew (b) (4)	01 Oct 2020 15:52:13
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'records have been requested, data is pending' (Site from Safety).	Brad Killebrew (b) (4)	01 Oct 2020 15:52:08
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (CT scan and any further imaging). Please include dates, units and reference ranges if applicable.' answered with 'records have been requested, data is pending' (Site from Safety).	Brad Killebrew (b) (4)	01 Oct 2020 15:52:03
User opened query 'PV Query: Please provide histology grade/stage of throat cancer, if available.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 15:24:43
Query 'Safety Medical Query: Please provide histology grade/stage of throat cancer, if available.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 15:24:17
Query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results when done. Please include units and reference ranges if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:57:54
Query 'Per ETRTR: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF when available (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:57:53

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Safety Medical Query: Please provide histology grade/stage of throat cancer, if available.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:07:06
User closed query 'PV Query: Please report the indication for the CT scan (ie. was the patient experiencing symptoms or was it routine follow-up of previous cancer).' (Site from Safety).		25 Aug 2020 19:16:24
Query 'PV Query: Please report the indication for the CT scan (ie. was the patient experiencing symptoms or was it routine follow-up of previous cancer).' answered with 'Routine follow-up from previous cancer ' (Site from Safety).	Brad Killebrew (b) (4)	25 Aug 2020 18:22:11
User opened query 'PV Query: Please report if the patient had any risk factors, other than prior throat cancer (ie. smoking, family history, etc.).' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:30:33
User opened query 'PV Query: Please report the indication for the CT scan (ie. was the patient experiencing symptoms or was it routine follow-up of previous cancer).' (Site from Safety).		24 Aug 2020 13:30:26
User opened query 'PV Query: Please provide copy of consultation note from oncology appointment.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:29:27
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		24 Aug 2020 13:29:16
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (CT scan and any further imaging). Please include dates, units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:27:22

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF when available (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from CRA).	(b) (4), (b) (6)	21 Aug 2020 03:09:34
User opened query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results when done. Please include units and reference ranges if applicable.' (Site from CRA).		21 Aug 2020 03:08:56
User entered 'Subject with a history of throat cancer was called on 18Aug2020 for Safety Call #3. Subject reported that during a recent CAT scan it was found that their cancer has recurred and has spread to their lungs. Patient is scheduled for oncology follow-up on 02Sep2020. More details, including treatment/procedures will be reported as the data becomes available.'	Brad Killebrew (b) (4)	18 Aug 2020 20:31:08

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager: User entered '1'	System	21 Aug 2020 01:01:19
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:01

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '1'	System	01 Oct 2020 15:49:32
Amendment Manager: User entered '0'	System	21 Aug 2020 01:01:19
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:01

US3122010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:57:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:01:01

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
Reviewed for Safety.		23 Mar 2021 14:03:19
User signature succeeded.	Matthew Hong (b) (4)	17 Mar 2021 14:58:22
User entered	(b) (4)	
'USA-US063-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	16 Mar 2021 18:09:56

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Metastases, HLT: Metastases to specified sites, PT: Metastases to lung, LLT: Metastases to lung - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 16:43:52
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 16:43:52
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	12 Mar 2021 17:18:56
Data point term sent to Coder	System	12 Mar 2021 16:20:32
User entered 'METASTASES TO LUNGS [RECURRENT OF THROAT CANCER]'	(b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'l'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:16:51
User closed query 'PV Query: Please provide causality assessment of Related or Not Related for study drug.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:03:08
Query 'PV Query: Please provide causality assessment of Related or Not Related for study drug.' answered with 'Patient was already scheduled for the scan that revealed the RECURRENCE OF THROAT CANCER. Scan happened 6 days after the IP dosing and considered not related to the IP' (Site from Safety).		22 Mar 2021 19:33:02
Signature has been broken.		22 Mar 2021 19:31:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error		22 Mar 2021 19:31:17
User opened query 'PV Query: Please provide causality assessment of Related or Not Related for study drug.' (Site from Safety).		18 Mar 2021 17:07:55
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:16:51
User closed query 'PV Query: Please provide causality assessment of Related or Not Related for study procedure.' (Site from Safety).	(b) (4)	23 Mar 2021 14:03:11
Query 'PV Query: Please provide causality assessment of Related or Not Related for study procedure.' answered with 'Patient was already scheduled for the scan that revealed the RECURRENCE OF THROAT CANCER. Scan happened 6 days after the IP dosing and considered not related to procedure' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 19:33:50
Signature has been broken.		22 Mar 2021 19:31:17
User entered 'Not Related (NOT RELATED)'		22 Mar 2021 19:31:17
reason for change: Data Entry Error		
User opened query 'PV Query: Please provide causality assessment of Related or Not Related for study procedure.' (Site from Safety).		18 Mar 2021 17:07:33
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, AE is NOT reflected in dosing discontinuation. Review and update. Else, clarify.' (Site from DM).		23 Mar 2021 17:59:10
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, AE is NOT reflected in dosing discontinuation. Review and update. Else, clarify.' answered with 'updated' (Site from DM).		22 Mar 2021 19:39:19
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, AE is NOT reflected in dosing discontinuation. Review and update. Else, clarify.' (Site from DM).		21 Mar 2021 05:12:04
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (METASTASES TO LUNGS) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		01 Apr 2021 03:31:29
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (METASTASES TO LUNGS) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'No treatment until September. (PEMBROLIZUMAB 24SEP2020)' (Site from DM).		30 Mar 2021 14:58:44
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (METASTASES TO LUNGS) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		30 Mar 2021 12:14:37
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:16:51
Signature has been broken.	(b) (4)	
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:39:50
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 19:39:50
	(b) (4)	12 Mar 2021 17:18:56
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

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Generated On: 11 Jun 2021 14:57:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:16:51
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4)	23 Mar 2021 17:59:09
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 19:40:55
Signature has been broken.		22 Mar 2021 19:39:50
User entered '0' reason for change: Data Entry Error		22 Mar 2021 19:39:50
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).		21 Mar 2021 05:11:58
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered '1'	(b) (4)	12 Mar 2021 16:20:25
	(b) (4), (b) (6)	

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WITH A HISTORY OF THROAT CANCER WAS CALLED ON 18AUG2020 FOR SAFETY CALL #3. SUBJECT REPORTED THAT DURING A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED AND HAS SPREAD TO THEIR LUNGS. PATIENT IS SCHEDULED FOR ONCOLOGY FOLLOW-UP ON 02SEP2020. MORE DETAILS, INCLUDING TREATMENT/PROCEDURES WILL BE REPORTED AS THE DATA BECOMES AVAILABLE. 9/24/2020 VISIT INFORMATION (ADDED FROM MEDICAL RECORDS RECEIVED 09OCT2020) DIAGNOSIS: SUBJECT IS DIAGNOSED WITH SQUAMOUS CELL CARCINOMA - LEFT TONSIL. STAGE: T2N2 (AJCC 8TH EDITION) T2N2C (7TH EDITION) MOLECULAR: P16+ GENE VARIANCE OF UNCERTAIN SIGNIFICANCE: CTNNB1: C.97T>A [P.SER33THR] CPS 2 ON CYCLE 1 OF PEMBROLIZUMAB. PLAN(DOCTOR'S NOTES): #SCC - LEFT TONSIL, T2N2 -NOW WITH BIOPSY PROVEN RECURRENT/METASTATIC DISEASE IN THE LUNGS -GIVEN LOW BURDEN, ASYMPTOMATIC DISEASE AND PD-L1 CPS 2, WILL PROCEED WITH FRONT LINE PEMBROLIZUMAB PER KN048' (WR#5445128)	System	11 Jun 2021 14:45:08
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User closed query 'PV Query: Follow up received 17 Mar 2021 indicates subject was unblinded (date unknown). Please add information to Unblinding Form of EDC Participant Decision Visit.' (Site from Safety).		31 Mar 2021 14:55:01
Query 'PV Query: Follow up received 17 Mar 2021 indicates subject was unblinded (date unknown). Please add information to Unblinding Form of EDC Participant Decision Visit.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 15:04:27
PRODUCTION RELEASE (v12.003 EAB) (1725)		1078 of 1444

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Follow up received 17 Mar 2021 indicates subject was unblinded (date unknown). Please add information to Unblinding Form of EDC Participant Decision Visit.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 13:01:03
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'SUBJECT WITH A HISTORY OF THROAT CANCER WAS CALLED ON 18AUG2020 FOR SAFETY CALL #3. SUBJECT REPORTED THAT DURING A RECENT CAT SCAN IT WAS FOUND THAT THEIR CANCER HAS RECURRED AND HAS SPREAD TO THEIR LUNGS. PATIENT IS SCHEDULED FOR ONCOLOGY FOLLOW-UP ON 02SEP2020. MORE DETAILS, INCLUDING TREATMENT/PROCEDURES WILL BE REPORTED AS THE DATA BECOMES AVAILABLE.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:20:25
9/24/2020 VISIT INFORMATION (ADDED FROM MEDICAL RECORDS RECEIVED 09OCT2020) DIAGNOSIS: SUBJECT IS DIAGNOSED WITH SQUAMOUS CELL CARCINOMA - LEFT TONSIL. STAGE: T2N2 (AJCC 8TH EDITION) T2N2C (7TH EDITION) MOLECULAR: P16+ GENE VARIANCE OF UNCERTAIN SIGNIFICANCE: CTNNB1: C.97T>A [P.SER33THR] CPS 2 ON CYCLE 1 OF PEMBROLIZUMAB.		
PLAN(DOCTOR'S NOTES): #SCC - LEFT TONSIL, T2N2 -NOW WITH BIOPSY PROVEN RECURRENT/METASTATIC DISEASE IN THE LUNGS -GIVEN LOW BURDEN, ASYMPTOMATIC DISEASE AND PD-L1 CPS 2, WILL PROCEED WITH FRONT LINE PEMBROLIZUMAB PER KN048'		

PRODUCTION RELEASE (v12.003
EAB) (1725)

1079 of 1444

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'I'	System	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered 'I'	System	12 Mar 2021 16:20:25

US3122010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:57:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Mar 2021 17:49:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 17:49:46
Data point term sent to Coder	System	12 Mar 2021 17:49:24
User entered 'Injection Site Pain'	(b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered '28 Jul 2020'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered '12:00' reason for change: Data Entry Error	System	12 Mar 2021 17:51:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 17:51:46
User entered empty.	System	12 Mar 2021 17:49:03
	(b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '28 Jul 2020 12:00'	System	12 Mar 2021 17:51:46
User entered empty.	System	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered '03 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered '11:59' reason for change: Data Entry Error	System	12 Mar 2021 17:51:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 17:51:46
User entered empty.	System	12 Mar 2021 17:49:03
	(b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '03 Aug 2020 11:59'	System	12 Mar 2021 17:51:46
User entered empty.	System	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'l'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:12:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '0'	System	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '0'	System	12 Mar 2021 17:49:03

US3122010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 14:57:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Jun 2021 14:57:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:09
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:37:34

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 18:38:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 18:38:16
Data point term sent to Coder	System	25 Nov 2020 18:36:44
Coding entries removed.	(b) (4), (b) (6)	25 Nov 2020 18:36:22
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 20:24:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 17:40:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 17:40:28
Data point term sent to Coder	System	13 Aug 2020 17:39:30
User entered 'Lipitor'	Aubrey Farray (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		15 Mar 2021 22:35:58
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:41:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:56:09
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		27 Jan 2021 10:21:25
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 Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).		30 Nov 2020 21:04:54
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 Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).		25 Nov 2020 18:36:33
DataPoint Un-verified.		25 Nov 2020 18:36:22
User entered 'hyperlipidemia' reason for change:		25 Nov 2020 18:36:22
Data Entry Error		
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 Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).		05 Nov 2020 11:28:28

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:28:11
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.		07 Sep 2020 03:40:29
' (Site from DM). DataPoint Verified.		01 Sep 2020 20:24:24
User entered 'Cholesterol'	Aubrey Fararray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered '20'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'mg (mg)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User closed query 'per source this is once daily. Please confirm and update as needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:54:12
DataPoint Verified.		10 Nov 2020 21:54:07
Query 'per source this is once daily. Please confirm and update as needed.' answered with 'updated' (Site from CRA).		09 Oct 2020 13:56:08
User entered 'once daily (QD)' reason for change: Per Query Resolution		09 Oct 2020 13:55:59
User opened query 'per source this is once daily. Please confirm and update as needed.' (Site from CRA).		01 Sep 2020 20:25:36
DataPoint Un-verified.		01 Sep 2020 20:24:41
DataPoint Verified.		01 Sep 2020 20:24:24
User entered 'four times daily (QID)'	Aubrey Farrah (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'Oral (ORAL)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		13 Aug 2020 23:15:07
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 17:38:32
User entered 'UN UNK 1990'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered '0'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '1'	System	09 Oct 2020 13:55:59
User entered '4'	System	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '1'	System	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:57:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '804 (804)'	System	13 Aug 2020 17:38:32

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:54:20
DataPoint Un-verified.		01 Sep 2020 20:27:02
DataPoint Verified.		01 Sep 2020 20:24:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INCREASING URIC ACID EXCRETION, PRODUCT: PROBENECID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:32:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:32:17
Data point term sent to Coder	System	13 Aug 2020 18:48:29
User entered 'Probenecid'	Aubrey Farrey (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 15:56:48
User closed query 'Per DM CLR: Prophylaxis is marked as NO. However, indication records "Gout Prophylaxis". Review if this should be updated to Yes or condition of Gout should be recorded in MH ecrf. Review and update entries as appropriate.' (Site from DM).		26 Jan 2021 01:12:25
Query 'Per DM CLR: Prophylaxis is marked as NO. However, indication records "Gout Prophylaxis". Review if this should be updated to Yes or condition of Gout should be recorded in MH ecrf. Review and update entries as appropriate.' answered with 'Corrected' (Site from DM).	Leah Corts (b) (4)	22 Jan 2021 15:24:25
DataPoint Un-verified.	Leah Corts (b) (4)	22 Jan 2021 15:24:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Leah Corts (b) (4)	22 Jan 2021 15:24:13
User opened query 'Per DM CLR: Prophylaxis is marked as NO. However, indication records "Gout Prophylaxis". Review if this should be updated to Yes or condition of Gout should be recorded in MH ecrf. Review and update entries as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 12:46:22
DataPoint Verified.		01 Sep 2020 20:24:24
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'Gout Prevention'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered '500'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'mg (mg)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User closed query 'Per source frequency is once per day please review and update as needed.' (Site from CRA).	(b) (4) (u) (4), (b) (6)	16 Nov 2020 17:17:57
DataPoint Verified.		16 Nov 2020 17:17:55
Query 'Per source frequency is once per day please review and update as needed.' answered with 'Updated' (Site from CRA).		16 Nov 2020 17:12:41
DataPoint Un-verified.		16 Nov 2020 17:12:35
User entered 'once daily (QD)' reason for change:		16 Nov 2020 17:12:35
Data Entry Error		
DataPoint Verified.		10 Nov 2020 21:58:35
User opened query 'Per source frequency is once per day please review and update as needed.' (Site from CRA).		10 Nov 2020 21:58:33
DataPoint Un-verified.		01 Sep 2020 20:27:29
DataPoint Verified.		01 Sep 2020 20:24:24
User entered 'four times daily (QID)'	Aubrey Farrray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'Oral (ORAL)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		13 Aug 2020 23:15:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:48:18
User entered 'UN UNK 1996'	Aubrey Fararray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered '0'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '1'	System	16 Nov 2020 17:12:35
User entered '4'	System	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '1'	System	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:57:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '804 (804)'	System	13 Aug 2020 18:48:18

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:57:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:57:21
Data point term sent to Coder	System	13 Aug 2020 18:56:42
User entered 'Zyrtec'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	0 Nov 2020 21:05:09
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'updated' (Site from DM).		5 Nov 2020 18:39:15
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).		7 Sep 2020 03:40:52
DataPoint Verified.		1 Sep 2020 20:24:24
User entered 'Seasonal Allergies'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered '10'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'mg (mg)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User closed query 'per source this is once daily. Please confirm and update as needed' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:56:25
DataPoint Verified.		10 Nov 2020 21:56:22
Query 'per source this is once daily. Please confirm and update as needed' answered with 'Updated' (Site from CRA).	Brad Killebrew (b) (4)	08 Sep 2020 20:38:41
User entered 'once daily (QD)' reason for change: Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 20:38:34
User opened query 'per source this is once daily. Please confirm and update as needed' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 20:28:06
DataPoint Un-verified.		01 Sep 2020 20:28:00
DataPoint Verified.		01 Sep 2020 20:24:24
User entered 'four times daily (QID)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'Oral (ORAL)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		13 Aug 2020 23:15:16
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:55:45
User entered 'UN UNK 1975'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered '0'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'Yes (Y)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered empty.	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 20:24:24
User entered 'No (N)'	Aubrey Farray (b) (4) (b) (4)	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '1'	System	08 Sep 2020 20:38:34
User entered '4'	System	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '1'	System	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:57:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '804 (804)'	System	13 Aug 2020 18:55:45

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: MONOCLONAL ANTIBODIES, PRODUCT: PEMBROLIZUMAB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 10:54:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 10:54:32
Data point term sent to Coder	System	30 Mar 2021 14:59:21
Coding entries removed.	(b) (4), (b) (6)	30 Mar 2021 14:59:16
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: MONOCLONAL ANTIBODIES, PRODUCT: PEMBROLIZUMAB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 09:57:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 09:57:30
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
Data point term sent to Coder	System	12 Mar 2021 16:36:52
User entered 'PEMBROLIZUMAB'	(b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 20:40:31
Signature has been broken.	(b) (4)	30 Mar 2021 14:59:16
User entered 'THROAT CANCER , METASTASES TO LUNGS' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 14:59:16
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Throat Cancer'	(b) (4)	12 Mar 2021 16:36:04
	(b) (4), (b) (6)	

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'unk'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:14:56
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:18:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:57:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered empty.	System	12 Mar 2021 16:36:04

US3122010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Jun 2021 14:57:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:43
User entered 'Yes (Y)'		10 Nov 2020 21:12:23

US3122010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 14:57:14

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:22:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	25 Nov 2020 18:21:21
User entered '12 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 18:21:21
DataPoint Verified.		10 Nov 2020 22:05:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 21:14:19
User entered ' Aug 2020' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 21:14:19

US3122010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 14:57:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:16:43
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:54:42
User closed query 'Per DM CLR: Please specify the location of CAT SCAN (e.g. CAT SCAN ON ABDOMEN, CAT SCAN ON CHEST, etc.). Update Concomitant Procedure eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 05:41:38
Query 'Per DM CLR: Please specify the location of CAT SCAN (e.g. CAT SCAN ON ABDOMEN, CAT SCAN ON CHEST, etc.). Update Concomitant Procedure eCRF as appropriate. ' answered with 'updated' (Site from DM).		12 Mar 2021 16:44:14
DataPoint Un-verified.		12 Mar 2021 16:44:00
Signature has been broken.		12 Mar 2021 16:44:00
User entered 'CT Chest WO Contrast in IMG CT HBR' reason for change: Data Entry Error		12 Mar 2021 16:44:00
User opened query 'Per DM CLR: Please specify the location of CAT SCAN (e.g. CAT SCAN ON ABDOMEN, CAT SCAN ON CHEST, etc.). Update Concomitant Procedure eCRF as appropriate. ' (Site from DM).		01 Mar 2021 09:03:31
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:59
User entered 'CAT Scan'		10 Nov 2020 21:14:19

US3122010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 14:57:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:22:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4) Leah Corts (b) (4)	15 Feb 2021 13:53:58
User closed query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 14:59:08
Query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify.' answered with 'Corrected' (Site from DM).	Leah Corts (b) (4)	03 Dec 2020 13:22:48
User entered 'Medical History (MH)' reason for change: Data Entry Error	Leah Corts (b) (4)	03 Dec 2020 13:22:40
User opened query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 08:49:10
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	25 Nov 2020 18:27:16
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 18:27:16
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	25 Nov 2020 18:27:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Nov 2020 18:27:01
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error		25 Nov 2020 18:27:01
DataPoint Verified.		10 Nov 2020 22:05:59
User entered 'Other (OTHER)'		10 Nov 2020 21:14:19

US3122010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 14:57:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:22:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Un-verified.	(b) (4) Leah Corts (b) (4)	03 Dec 2020 13:22:40
User entered empty; reason for change Data Entry Error	Leah Corts (b) (4)	03 Dec 2020 13:22:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:59
User entered 'Follow up from previous Med Hx'		10 Nov 2020 21:14:19

US3122010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 14:57:14

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:22:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:26:19

US3122010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 14:57:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:22:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User entered 'Guided lung biopsy: positive for squamous cell carcinoma consistent with metastasis , CPS 2, p40/p16 and hrHPV positive'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:26:19

US3122010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 14:57:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:22:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:26:19

US3122010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 14:57:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:22:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:26:19

US3122010

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 14:57:14

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Nov 2020 22:05:16
User closed query 'Per DM: Please check the "date of dosing discontinuation."' (Site from DM).		27 Oct 2020 02:50:28
Query 'Per DM: Please check the "date of dosing discontinuation."' answered with 'Changed to date we collected AE info.' (Site from DM).	Leah Corts (b) (4)	22 Oct 2020 17:20:15
User entered '18 Aug 2020' reason for change: Data Entry Error	Leah Corts (b) (4)	22 Oct 2020 17:17:30
User opened query 'Per DM: Please check the "date of dosing discontinuation."' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 14:39:44
User entered '12 Aug 2020'	Brad Killebrew (b) (4)	01 Oct 2020 15:50:51

US3122010

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 14:57:14

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:17:41
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:16:51
DataPoint Un-verified.	(b) (4)	22 Mar 2021 19:39:13
Signature has been broken.	(b) (4), (b) (6)	22 Mar 2021 19:39:13
User entered 'AE (specify) (ADVERSE EVENT)'		22 Mar 2021 19:39:13
reason for change: Data Entry Error		
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:05:16
User entered 'SAE (specify) (SAE)'	Brad Killebrew (b) (4)	01 Oct 2020 15:50:51

US3122010

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:24:34
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User closed query 'Per CDM Re-query: update is noted; however please record record line number instead per CCGs (i.e. AE#1 or SAE#1, etc.)' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 12:17:26
Query 'Per CDM Re-query: update is noted; however please record record line number instead per CCGs (i.e. AE#1 or SAE#1, etc.)' answered with 'updated' (Site from DM).		25 Nov 2020 16:33:40
User entered 'AE#1' reason for change: Per Query Resolution		25 Nov 2020 16:33:34
User opened query 'Per CDM Re-query: update is noted; however please record record line number instead per CCGs (i.e. AE#1 or SAE#1, etc.)' (Site from DM).		23 Nov 2020 01:40:36
Query 'Per CDM: per CCGs please provide the record number instead of details.' canceled (Site from DM).		23 Nov 2020 01:40:04
User entered '1' reason for change: Per Query Resolution		20 Nov 2020 18:06:54
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	20 Nov 2020 18:06:11
User entered 'SAE' reason for change: Per Query Resolution	(b) (4), (b) (6)	20 Nov 2020 18:06:11
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	20 Nov 2020 18:05:01
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:01
User entered empty; reason for change Per Query Resolution		20 Nov 2020 18:05:01

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
User opened query 'Per CDM: per CCGs please provide the record number instead of details.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:27:37
DataPoint Verified.		10 Nov 2020 22:05:16
User entered 'Lung Cancer'	Brad Killebrew (b) (4)	01 Oct 2020 15:50:51

US3122010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 14:57:14

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		15 Apr 2021 16:35:08
DataPoint Un-verified.		06 Apr 2021 17:28:54
DataPoint Verified.		06 Apr 2021 17:18:50
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:33:37

US3122010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 14:57:14

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		15 Apr 2021 16:35:08
DataPoint Un-verified.		06 Apr 2021 17:28:52
DataPoint Verified.		06 Apr 2021 17:18:50
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:33:37

US3122010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 14:57:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		15 Apr 2021 16:35:08
DataPoint Un-verified.		06 Apr 2021 17:28:55
DataPoint Verified.		06 Apr 2021 17:18:50
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered 'Reoccurrence of throat cancer resulted in unblinding. Subject could continue safety follow up at physician's discretion which was removed on 11/25/20.'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:33:37

US3122010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 14:57:14

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		15 Apr 2021 16:35:08
DataPoint Un-verified.		06 Apr 2021 17:28:57
DataPoint Verified.		06 Apr 2021 17:18:50
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:33:37

US3122010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 14:57:14

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:18:50
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:33:37

US3122010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 14:57:14

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:18:50
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:33:37

US3122010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 14:57:14

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 17:18:50
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 20:47:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:33:37

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (o) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 14:57:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
User entered '19/Aug/2020 13:10'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 14:57:14

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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		25 Aug 2020 19:16:39
User entered 'I'		19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (o) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 14:57:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
User entered '25/Aug/2020 15:16'	System	25 Aug 2020 19:16:55

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 14:57:14

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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
User entered 'I'		25 Aug 2020 19:16:55

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 14:57:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
User entered '16/Sep/2020 15:01'	System	16 Sep 2020 19:01:41

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 14:57:14

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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
User entered 'I'		16 Sep 2020 19:01:41

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (o) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (o) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 11 Jun 2021 14:57:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
User entered '01/Oct/2020 13:36'	System	01 Oct 2020 17:36:08

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 11 Jun 2021 14:57:14

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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:39:47
DataPoint Verified.		02 Oct 2020 20:27:18
User entered 'I'		01 Oct 2020 17:36:08

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 11 Jun 2021 14:57:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:00:12
User entered '23/Oct/2020 20:40'	System	23 Oct 2020 20:40:02

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 11 Jun 2021 14:57:14

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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	24 Nov 2020 02:49:40
DataPoint Verified.		10 Nov 2020 22:00:14
User entered 'I'		23 Oct 2020 20:40:02

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 11 Jun 2021 14:57:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:28:51
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User entered '23/Nov/2020 21:49'	(b) (4) System	24 Nov 2020 02:49:49

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 11 Jun 2021 14:57:14

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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:29:00
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:04:17
User entered 'I'		24 Nov 2020 02:49:49

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 11 Jun 2021 14:57:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:29:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User entered '30/Nov/2020 15:04'	(b) (4) System	30 Nov 2020 20:04:30

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 11 Jun 2021 14:57:14

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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:29:14
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:23:13
User entered 'I'		30 Nov 2020 20:04:30

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (o) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 11 Jun 2021 14:57:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:30:18
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
User entered '16/Feb/2021 13:22'	(b) (4) System	16 Feb 2021 18:22:54

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 11 Jun 2021 14:57:14

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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		10 Mar 2021 16:30:23
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:23:13
User entered 'I'		16 Feb 2021 18:22:54

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 11 Jun 2021 14:57:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 16:10:58
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:54:42
User entered '15/Mar/2021 11:26'	(b) (4) System	15 Mar 2021 15:26:50

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 11 Jun 2021 14:57:14

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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 16:10:58
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:54:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:26:55
User entered 'I'		15 Mar 2021 15:26:50

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 11 Jun 2021 14:57:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 16:10:58
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:54:42
User entered '16/Mar/2021 14:10'	(b) (4) System	16 Mar 2021 18:11:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 11 Jun 2021 14:57:14

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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 16:10:58
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:54:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:11:10
User entered 'I'		16 Mar 2021 18:11:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 11 Jun 2021 14:57:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 16:10:58
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:05:23
User entered '18/Mar/2021 11:54'	(b) (4) System	18 Mar 2021 16:55:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 11 Jun 2021 14:57:14

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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 16:10:58
Reviewed for Safety.		23 Mar 2021 14:04:01
User signature succeeded.	Matthew Hong (b) (4)	19 Mar 2021 17:05:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:55:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:36
User entered 'USA-US063-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'No (N)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		19 Aug 2020 17:09:41
User entered 'Yes (Y)'	System	19 Aug 2020 17:07:59

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Wayne'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Amendment Manager: User entered 'Harper'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '3100 Duraleigh System Rd'		14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'Raleigh'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered 'NC'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		16 Sep 2020 19:01:28
Amendment Manager: User entered '27612'	System	14 Sep 2020 21:39:50
User entered empty.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:01

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:27:18
Reviewed for Safety.		01 Oct 2020 17:36:01
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:05:16
Un-reviewed for Safety.	System	16 Sep 2020 19:01:41
User entered 'US' (non-conformant).	System	16 Sep 2020 19:01:41
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:01:28
Un-reviewed for Safety.	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 14:32:14
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 19:16:39
User entered 'US' (non-conformant).	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:57:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
User entered '12'	System	23 Mar 2021 14:04:16
User entered '11'	System	18 Mar 2021 16:55:01
User entered '10'	System	16 Mar 2021 18:11:01
User entered '9'	System	15 Mar 2021 15:26:50
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 19:09:41
	(b) (4)	
User entered '8'	System	16 Feb 2021 18:22:54
User entered '7'	System	30 Nov 2020 20:04:30
User entered '6'	System	24 Nov 2020 02:49:49
User entered '5'	System	23 Oct 2020 20:40:02
User entered '4'	System	01 Oct 2020 17:36:08
User entered '3'	System	16 Sep 2020 19:01:41
User entered '2'	System	25 Aug 2020 19:16:55
User entered '1'	System	19 Aug 2020 17:10:27

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Generated On: 11 Jun 2021 14:57:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 16:10:58
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:16:51
User entered '23/Mar/2021 10:04'	(b) (4) System	23 Mar 2021 14:04:16

US3122010

Folder: SAE USA-US063-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Generated On: 11 Jun 2021 14:57:14

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)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:45:07
DataPoint Verified.		06 Apr 2021 16:10:58
User signature succeeded.	Matthew Hong (b) (4)	23 Mar 2021 19:16:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:04:16