US3042190 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

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US3042190
Form: Participant Creation
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

Participant ID	US3042190

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0184955

US3042190
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0184956

US3042190
Folder: Screening
Form: Demographics
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Date of Birth (MMM yyyy)	(b) (6) 1992
Age	27
Age Units	YEARS
Age (Derived)	27
Sex	Female ■ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
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

FDA-CBER-2022-1614-0184957

US3042190
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Date of Informed Consent *(dd MMM yyyy)*	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ■ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

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US3042190
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **28 Apr 2021 09:57:57**
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Did the participant meet all eligibility criteria?	Yes ■ No ☐

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US3042190
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **28 Apr 2021 09:57:57**
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Were any significant conditions reported?	Yes ■ No ☐

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US3042190
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3042190
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Condition	UTERINE/VAGINAL BLEEDING
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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US3042190
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☑
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

US3042190
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Were vital signs assessed?	Yes ☑ No ☐
Date of assessment *(dd MMM yyyy)*	13 AUG 2020
Time of assessment *(00:00-23:59)*	18:25 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 18:25
Height *(xxx.x)*	167.6 cm
Weight *(xxx.x)*	88.2 kg
BMI *(xxx.x)*	31.39934 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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US3042190
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	13 AUG 2020

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

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US3042190
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Date of assessment *(dd MMM yyyy)*	13 AUG 2020
Is the participant of childbearing potential?	Yes ☐ No ■
If No, what is the reason?	Surgically sterile ■ Post-menopausal ☐ Partner medically sterile ☐ Not reached age of Menarche ☐ Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	UN JUN 2020
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

US3042190
Folder: Screening
Form: Pregnancy Test
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Was the pregnancy test performed?	Yes ■ No ☐
Date of test *(dd MMM yyyy)*	13 AUG 2020
Test performed	Urine ■ Serum ☐
Result	Positive ☐ Negative ■
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

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US3042190
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **28 Apr 2021 09:57:57**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ■ No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ■
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ■
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ■
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ■
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ■
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ■
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ■
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ■
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ■
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ■
Other	Yes ☐ No ■
Specify	
Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

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

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US3042190
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

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US3042190
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **28 Apr 2021 09:57:57**
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What was the date of randomization? *(dd MMM yyyy)*	13 AUG 2020
What was the participant's randomization number?	104161
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ■ >=18 and <65 years and at risk ☐ >=65 years ☐

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ☐ No ■
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ☐ No ■
Severe obesity (body mass index > or = 40kg/m2	Yes ☐ No ■
Diabetes (Type I, Type 2, or gestational)	Yes ☐ No ■
Liver Disease	Yes ☐ No ■
Human Immunodeficiency Virus (HIV) infection	Yes ☐ No ■

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US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **28 Apr 2021 09:57:57**
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Height	ND - Not Done
Weight	ND - Not Done

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US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	13 AUG 2020
Time of assessment *(00:00-23:59)*	18:25 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 18:25
Temperature *(xxx.x)*	37.2 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	94 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG

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US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	13 AUG 2020
Time of assessment *(00:00-23:59)*	19:50 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 19:50
Temperature *(xxx.x)*	37.2 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	77 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0184974

US3042190
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	13 AUG 2020

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

FDA-CBER-2022-1614-0184975

US3042190
Folder: Visit 1 Day 1
Form: Pregnancy Test
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Was the pregnancy test performed?	Yes ☐ No ■
Date of test *(dd MMM yyyy)*	
Test performed	Urine ☐ Serum ☐
Result	Positive ☐ Negative ☐
Was FSH sample collected?	Yes ☐ No ■
Collection date	
Collection time	
Collection date and time (derived)	

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US3042190
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **28 Apr 2021 09:57:57**
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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)*	13 AUG 2020
What was the treatment time? *(00:00-23:59)*	19:16 (24 HR)
Treatment Date and Time (derived)	13 AUG 2020 19:16
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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US3042190
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	13 AUG 2020
Collection time *(00:00-23:59)*	19:02 (24 HR)
Collection date and time (derived)	13 AUG 2020 19:02

FDA-CBER-2022-1614-0184978

US3042190
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Collection date *(dd MMM yyyy)*			13 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:52	13 AUG 2020 18:52
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0184979

US3042190
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 09:57:57**
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Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0184980

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:56:56

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

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	13 AUG 2020 19:39
PC Open Date & Time	13 AUG 2020 19:36
PC Close Date & Time	13 AUG 2020 22:06

FDA-CBER-2022-1614-0184981

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**	97.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	14 AUG 2020 10:00
PC Open Date & Time	13 AUG 2020 23:01
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-0184982

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	14 AUG 2020 18:52
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

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US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	15 AUG 2020 20:13
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

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US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	16 AUG 2020 19:13
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

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Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 AUG 2020 07:06
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-0184986

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:56:56

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**	97.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 AUG 2020 19:36
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-0184987

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 AUG 2020 19:58
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	13 AUG 2020 19:39
PC Open Date & Time	13 AUG 2020 19:36
PC Close Date & Time	13 AUG 2020 22:06

FDA-CBER-2022-1614-0184989

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	14 AUG 2020 10:00
PC Open Date & Time	13 AUG 2020 23:01
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-0184990

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	14 AUG 2020 18:53
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-0184991

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	15 AUG 2020 20:13
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-0184992

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	16 AUG 2020 19:13
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-0184993

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	18 AUG 2020 07:06
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	18 AUG 2020 19:37
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-0184995

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:56:56

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	19 AUG 2020 19:58
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

FDA-CBER-2022-1614-0184996

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 ☐

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:56:56

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	13 AUG 2020 19:40
PC Open Date & Time	13 AUG 2020 19:36
PC Close Date & Time	13 AUG 2020 22:06

FDA-CBER-2022-1614-0184998

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 ☐

FDA-CBER-2022-1614-0184999

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:56:56

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	14 AUG 2020 10:00
PC Open Date & Time	13 AUG 2020 23:01
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-0185000

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:56:56

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 ■

FDA-CBER-2022-1614-0185001

	Yes ☐
PC Time stamp	14 AUG 2020 18:54
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56

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 ■

FDA-CBER-2022-1614-0185003

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56

	Yes ☐
PC Time stamp	15 AUG 2020 20:14
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-0185004

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:56:56

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 ■

FDA-CBER-2022-1614-0185005

	Yes ☐
PC Time stamp	16 AUG 2020 19:13
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56

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 ■

FDA-CBER-2022-1614-0185007

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56

	Yes ☐
PC Time stamp	18 AUG 2020 07:06
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-0185008

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:56:56

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 ■

FDA-CBER-2022-1614-0185009

	Yes ☐
PC Time stamp	18 AUG 2020 19:37
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56

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 ■

FDA-CBER-2022-1614-0185011

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56

	Yes ☐
PC Time stamp	19 AUG 2020 19:58
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

FDA-CBER-2022-1614-0185012

US3042190
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	20 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0185013

US3042190
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0185014

US3042190
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	27 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

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US3042190
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

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US3042190
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 09:57:57**
Generated On: 09 Jun 2021 14:56:56

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	03 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

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Is the participant continuing to the next visit?	Yes ☐ No ■
Continuing Flag	

US3042190
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 09 Jun 2021 14:56:56

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

US3042190
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 14:56:56

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐ Clinical Visit - Unscheduled ☐ Safety Call ☐ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐ No ☐

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US3042190
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 14:56:56

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-0185021

US3042190
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:56:56

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	

FDA-CBER-2022-1614-0185022

US3042190
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:56:56

Date of updated informed consent *(dd MMM yyyy)*	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	
Was the participant unblinded?	Yes ☐ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☐
Date of unblinding *(dd MMM yyyy)*	
Participant randomization assignment	mRNA-1273 ☐ Placebo ☐
Actual Dose 1	mRNA-1273 ☐ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☐ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ☐
Placebo Only Flag	
Continuing with mRNA-1273	

Was the sample collected?	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

Was the sample collected?	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	
Collection time *(00:00 - 23:59)*	
Collection Date and Time (derived)	

US3042190
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

Did the participant experience any adverse events?	Yes ■ No ☐

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-0185026

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

AEID	USA-US052-2020-MRNA-1273-P301000003
Adverse event	MULTIPLE PULMONARY EMBOLI
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)*	09 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	10 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	9 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	10 SEP 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

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

Narrative

	PATIENT CALLED TO REPORT ADMITTANCE INTO THE HOSPITAL FOR MULTIPLE PULMONARY EMOBLI. PATIENT STATES STARTED NEW ORAL CONTRACEPTION PILL LAST WEEK AND BEGAN EXPERIENCING BACK PAIN. PATIENT WENT TO PCP FOR CONSULT AND WAS ADMITTED TO HOSPITAL.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

Were any prior/concomitant medications and/or vaccinations taken?	Yes ■ No ☐

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

FDA-CBER-2022-1614-0185030

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

Name of Medication	HYDROXIZINE
Prophylaxis	Yes ☐ No ■
Indication	ANXIETY
Dose per administration	25
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-0185031

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

Name of Medication	LEXAPRO
Prophylaxis	Yes ☐ No ■
Indication	ANXIETY
Dose per administration	30
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 ☐

FDA-CBER-2022-1614-0185033

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	MIRENA
Prophylaxis	Yes ■ No ☐
Indication	CONTRACEPTION
Dose per administration	52
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	Q5YEARS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ■
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JUN 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	09 SEP 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

Name of Medication	ELIQUIS
Prophylaxis	Yes ☐ No ■
Indication	MULTIPLE PULMONARY EMBOLI
Dose per administration	5
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	10 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

Name of Medication	PROGESTERONE
Prophylaxis	Yes ☐ No ■
Indication	MULTIPLE PULMONARY EMBOLI
Dose per administration	5
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

FDA-CBER-2022-1614-0185039

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	10 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3042190
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

Were any concomitant procedures performed?	Yes ☐ No ■

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-0185041

US3042190
Folder: End of Study (1)
Form: Dosing Discontinuation
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

Date of dosing discontinuation (dd MMM yyyy)	17 SEP 2020
Primary reason for dosing discontinuation	AE (specify) ☐ SAE (specify) ■ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Due to SARS-COV-2 ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SAE #1

FDA-CBER-2022-1614-0185042

US3042190
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

Date of study discontinuation/completion *(dd MMM yyyy)*	17 SEP 2020
Reason for discontinuation	AE (specify) ☐ SAE (specify) ■ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SAE #1
If reason for discontinuation is Death, main cause of death	Adverse event ☐ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	
Was autopsy performed?	Yes ☐ No ☐ Unknown ☐

FDA-CBER-2022-1614-0185043

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

SAEID	USA-US052-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

FDA-CBER-2022-1614-0185044

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

SAEID	USA-US052-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	11/SEP/2020 11:49
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

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

SAEID	USA-US052-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	16/SEP/2020 15:26
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

FDA-CBER-2022-1614-0185046

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

SAEID	USA-US052-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	18/SEP/2020 11:52
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

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

SAEID	USA-US052-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	05/OCT/2020 08:26
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

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

SAEID	USA-US052-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	06/OCT/2020 16:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (6)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

SAEID	USA-US052-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	19/OCT/2020 16:10
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

FDA-CBER-2022-1614-0185050

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (7)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

SAEID	USA-US052-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	21/OCT/2020 14:41
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

FDA-CBER-2022-1614-0185051

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (8)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

SAEID	USA-US052-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	03/NOV/2020 16:12
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

FDA-CBER-2022-1614-0185052

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (9)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

SAEID	USA-US052-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	11/DEC/2020 09:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-0185053

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (10)
Data signed: (b) (4) **28 Apr 2021 09:57:56**
Generated On: 09 Jun 2021 14:56:56

SAEID	USA-US052-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	330 DAKOTA DUNES SUITE400
Site Address: City	NORTH SIOUX
Site Address: State	IA
Site Address: Postal Code	57049
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	18/DEC/2020 05:49
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

FDA-CBER-2022-1614-0185054

Audit

US3042190 (Prod: Meridian Clinical Research)

FDA-CBER-2022-1614-0185055

US3042190
Form: Participant Creation
Generated On: 09 Jun 2021 14:56:56
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:24:56
User entered 'US3042190'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 00:09:08

US3042190
Form: Participant Creation
Generated On: 09 Jun 2021 14:56:56

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18

FDA-CBER-2022-1614-0185057

US3042190
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:56:56
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:30
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:05:55

US3042190
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:56:56
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:30
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 00:09:09

US3042190
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:56:56
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:30
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:05:55

US3042190
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:56:56
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered 'SCRN'	System	14 Aug 2020 22:05:55

FDA-CBER-2022-1614-0185061

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered (b) (6) 1992'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 00:09:10

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered '27'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:00

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered 'YEARS'	System	14 Aug 2020 22:06:00

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered '27'	(b) (4), (b) (6) System	14 Aug 2020 00:32:18

FDA-CBER-2022-1614-0185065

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered 'Female (F)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:00

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:00

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered '1'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:00

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:00

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:00

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:00

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:00

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:00

FDA-CBER-2022-1614-0185073

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:00

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:00

US3042190
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:56:56
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:43
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:00

US3042190
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:56:56
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:16:02
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:18

US3042190
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:56:56
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered 'Aug 2020'	(b) (4), (b) (6) System	14 Aug 2020 00:32:18

US3042190
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:56:56
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered '2020'	(b) (4), (b) (6) System	14 Aug 2020 00:32:18

FDA-CBER-2022-1614-0185079

US3042190
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:56:56
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:16:02
User entered 'Amendment 2 (2)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:18

US3042190
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:56:56
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:16:02
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:18

US3042190
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:56:56
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:16:02
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:18

US3042190
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:56:56
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:16:02
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:18

US3042190
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:56:56
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:16:02
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:18

US3042190
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:56:56
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:16:02
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 00:09:09

US3042190
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:56:56
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered '1'	System	14 Aug 2020 00:32:20

FDA-CBER-2022-1614-0185086

US3042190
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 14:56:56
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:16:15
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:20

US3042190
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 14:56:56
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:16:22
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:11

US3042190
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:56:56
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:21:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:21:37
Data point term sent to Coder	System	14 Aug 2020 22:07:17
User entered 'ANXIETY'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:22

US3042190
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:56:56
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered 'UN UNK 2018'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:22

US3042190
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:56:56
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:22

US3042190
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:56:56
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:22

US3042190
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:56:56
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:22

US3042190
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:56:56
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:22

US3042190
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:56:56
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered 'Jan 2018'	System	14 Aug 2020 22:06:22

FDA-CBER-2022-1614-0185095

US3042190
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:56:56
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered '2018'	(b) (4), (b) (6) System	14 Aug 2020 22:06:22

US3042190
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:56:56
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered empty.	(b) (4), (b) (6) System	14 Aug 2020 22:06:22

FDA-CBER-2022-1614-0185097

US3042190
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:56:56
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered empty.	(b) (4), (b) (6) System	14 Aug 2020 22:06:22

FDA-CBER-2022-1614-0185098

US3042190
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:56:56
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Uterine haemorrhage, LLT: Uterine bleeding - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 22:25:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 22:25:32
Data point term sent to Coder	System	14 Aug 2020 22:07:19
User entered 'UTERINE/VAGINAL BLEEDING'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:51

US3042190
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:56:56
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered 'UN Jun 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:51

US3042190
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:56:56
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:51

FDA-CBER-2022-1614-0185101

US3042190
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:56:56
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:51

US3042190
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:56:56
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:51

US3042190
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:56:56
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:06:51

US3042190
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:56:56
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered 'Jun 2020'	(b) (4), (b) (6) System	14 Aug 2020 22:06:51

US3042190
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:56:56
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered '2020'	(b) (4), (b) (6) System	14 Aug 2020 22:06:51

FDA-CBER-2022-1614-0185106

US3042190
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:56:56
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered empty.	(b) (4), (b) (6) System	14 Aug 2020 22:06:51

FDA-CBER-2022-1614-0185107

US3042190
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:56:56
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered empty.	(b) (4), (b) (6) System	14 Aug 2020 22:06:51

FDA-CBER-2022-1614-0185108

US3042190
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:56:56
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 18:42:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 18:42:28
Data point term sent to Coder	System	12 Oct 2020 18:41:36
Coding entries removed.	Rylea Gulick (b) (4)	12 Oct 2020 18:41:24
User entered 'BILATERAL TUBAL LIGATION' reason for change: Data Entry Error	Rylea Gulick (b) (4)	12 Oct 2020 18:41:24
User closed query 'Per DM CLR: Please review if matching data is recorded in Childbearing Potential eCRF. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 10:39:05
Query 'Per DM CLR: Please review if matching data is recorded in Childbearing Potential eCRF. Reconcile and update as appropriate. ' answered with 'WILL REVIEW' (Site from DM).	Rylea Gulick (b) (4)	02 Sep 2020 23:39:09
User opened query 'Per DM CLR: Please review if matching data is recorded in Childbearing Potential eCRF. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 05:30:16
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:21:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:21:38
Data point term sent to Coder	System	14 Aug 2020 22:08:24
User entered 'TUBAL LIGATION'	Rylea Gulick (b) (4)	14 Aug 2020 22:08:21

FDA-CBER-2022-1614-0185109

US3042190
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:56:56
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	02 Sep 2020 23:38:59
User entered 'UN Jun 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:38:59
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	14 Aug 2020 22:08:21
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:21

US3042190
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:56:56
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:21

FDA-CBER-2022-1614-0185111

US3042190
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:56:56
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 23:38:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 23:38:59
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:38:59
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 22:08:21
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:21

US3042190
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:56:56
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered 'UN Jun 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:38:59
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:21

US3042190
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:56:56
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:21

US3042190
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:56:56
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
	(b) (4), (b) (6)	
User entered 'Jun 2020'	System	02 Sep 2020 23:38:59
User entered empty.	System	14 Aug 2020 22:08:21

US3042190
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:56:56
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered '2020'	System	02 Sep 2020 23:38:59
User entered empty.	System	14 Aug 2020 22:08:21

US3042190
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:56:56
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered 'Jun 2020'	System	02 Sep 2020 23:38:59
User entered empty.	System	14 Aug 2020 22:08:21

US3042190
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:56:56
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered '2020'	System	02 Sep 2020 23:38:59
User entered empty.	System	14 Aug 2020 22:08:21

FDA-CBER-2022-1614-0185118

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:18
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:47

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:18
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:47

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:18
User entered '18:25'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:47

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered '13 Aug 2020 18:25'	(b) (4), (b) (6) System	14 Aug 2020 22:08:47

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:18
User entered '167.6' cm	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:47
DataPoint set to visible.	System	14 Aug 2020 00:32:20

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:18
User entered '88.2' kg	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:47
DataPoint set to visible.	System	14 Aug 2020 00:32:20

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
Amendment Manager: User entered '31.39934'	System	16 Sep 2020 23:56:36
User entered '31.4'	System	14 Aug 2020 22:08:47
DataPoint set to visible.	System	14 Aug 2020 00:32:20

FDA-CBER-2022-1614-0185125

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered 'kg/m2'	System	14 Aug 2020 22:08:47
DataPoint set to visible.	System	14 Aug 2020 00:32:20

FDA-CBER-2022-1614-0185126

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:18
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:55:58
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:15:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:15:17
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:10:28
User entered '37.2' C	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:47

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:18
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:15:17
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:47

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:18
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:47

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:15:17
User entered '94'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:47

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered 'bpm'	(b) (4), (b) (6) System	14 Aug 2020 22:08:47

FDA-CBER-2022-1614-0185131

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:15:17
User entered '12'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:47

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Aug 2020 22:08:47

FDA-CBER-2022-1614-0185133

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:15:17
User entered '133'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:47

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered 'mmHg'	System	14 Aug 2020 22:08:47

FDA-CBER-2022-1614-0185135

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:15:17
User entered '82'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:47

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered 'mmHg'	System	14 Aug 2020 22:08:47

FDA-CBER-2022-1614-0185137

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28

FDA-CBER-2022-1614-0185138

US3042190
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:56:56
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28

FDA-CBER-2022-1614-0185139

US3042190
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 14:56:56
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:40
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:51

US3042190
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 14:56:56
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:40
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:51

US3042190
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:56:56
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:54
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:57

US3042190
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:56:56
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:54
User closed query 'Per CDM Please note if the subject has tubal ligation then it is considered as non childbearing, Kindly update the field and update the reason accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:32:26
Query 'Per CDM Please note if the subject has tubal ligation then it is considered as non childbearing, Kindly update the field and update the reason accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 17:36:29
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 17:35:56
User opened query 'Per CDM Please note if the subject has tubal ligation then it is considered as non childbearing, Kindly update the field and update the reason accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 04:46:50
User closed query 'Per CDM please note as per the Medical history the Patient has had tubal ligation . Kindly confirm and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 04:46:50
Query 'Per CDM please note as per the Medical history the Patient has had tubal ligation . Kindly confirm and update accordingly.' answered with 'Tubal Ligation is Birth control, not sterilization' (Site from DM).	Meagan Miller (b) (4) (b) (4)	10 Sep 2020 22:33:05
User opened query 'Per CDM please note as per the Medical history the Patient has had tubal ligation . Kindly confirm and update accordingly.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 10:41:16
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:57

US3042190
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:56:56
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:54
User closed query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:39:02
Query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' answered with 'THIS IS A BILATERAL TUBAL LIGATION. ENTRY WILL BE UPDATED IN MED HX' (Site from DM).	Rylea Gulick (b) (4)	12 Oct 2020 18:41:10
User opened query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 07:11:00
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	16 Sep 2020 17:36:02
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Sep 2020 17:36:02
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	16 Sep 2020 17:35:56
User entered empty.	Rylea Gulick (b) (4)	14 Aug 2020 22:08:57

US3042190
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:56:56
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:54
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:57

US3042190
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:56:56
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:54
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	16 Sep 2020 17:36:21
User entered 'UN Jun 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 17:36:21
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	16 Sep 2020 17:36:02
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:57

US3042190
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:56:56
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:54
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:57

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US3042190
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:56:56
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:54
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:57

US3042190
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:56:56
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:17:54
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:08:57

FDA-CBER-2022-1614-0185149

US3042190
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:23
User closed query 'Per CDM: "Is the participant of Childbearing potential?" is marked as "No"; however, pregnancy test data is recorded. Please review, reconcile and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:18:24
Query 'Per CDM: "Is the participant of Childbearing potential?" is marked as "No"; however, pregnancy test data is recorded. Please review, reconcile and update as appropriate, else clarify. Thank you.' answered with 'pregnancy test was done inadvertently' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	26 Oct 2020 17:19:52
User opened query 'Per CDM: "Is the participant of Childbearing potential?" is marked as "No"; however, pregnancy test data is recorded. Please review, reconcile and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:18:43
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:20

US3042190
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:23
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:20

US3042190
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:23
User entered 'Urine (URINE)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:20

US3042190
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:23
User entered 'Negative (NEGATIVE)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:20

US3042190
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:23
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:20

US3042190
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:23
User closed query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed,Kindly confirm if the FSH collected is Yes/NO, If NO, kindly remove the date and time. Thanks ' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 10:36:57
Query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed,Kindly confirm if the FSH collected is Yes/NO, If NO, kindly remove the date and time. Thanks ' answered with 'DATA REMOVED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:39:50
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:39:46
User opened query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed,Kindly confirm if the FSH collected is Yes/NO, If NO, kindly remove the date and time. Thanks ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:25:22
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:20

US3042190
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:23
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:39:46
User entered '18:30'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:20

US3042190
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User entered empty.	System	02 Sep 2020 23:39:46
User entered '13 Aug 2020 18:30'	System	14 Aug 2020 22:09:20

FDA-CBER-2022-1614-0185157

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

FDA-CBER-2022-1614-0185161

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered '1'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

US3042190
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:56:56
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:03:28
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:18:44
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:45

FDA-CBER-2022-1614-0185178

US3042190
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:56:56
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:19
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:56

US3042190
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:56:56
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:19
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:56

US3042190
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:56:56
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:19
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:09:56

US3042190
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:56:56
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered 'VISIT1'	System	14 Aug 2020 22:09:56

FDA-CBER-2022-1614-0185182

US3042190
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:56:56
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:28
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 00:14:15

US3042190
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:56:56
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:28
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:24:57
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:24:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 00:14:15
User entered '104161' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 00:14:15

US3042190
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:56:56
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:28
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 00:14:15

FDA-CBER-2022-1614-0185185

US3042190
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:28
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:10:03

US3042190
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:56:56

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) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:28
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:10:03

FDA-CBER-2022-1614-0185187

US3042190
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:56:56
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:28
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:10:03

FDA-CBER-2022-1614-0185188

US3042190
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:56:56
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:28
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:10:03

US3042190
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:56:56
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:28
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:10:03

FDA-CBER-2022-1614-0185190

US3042190
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:56:56
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:19:28
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:27:00
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'ENTRY UPDATED ' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	29 Oct 2020 17:38:13
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Oct 2020 17:38:10
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:48:58
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:35
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:12:27

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:56:56
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:52:32
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4)	27 Oct 2020 14:38:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	27 Oct 2020 14:38:33
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:31:42
User entered '167.6' cm	Rylea Gulick (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185192

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:56:56
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	27 Oct 2020 14:38:33
User entered '88.2' kg	Rylea Gulick (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:56:56
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:52:32
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4)	27 Oct 2020 14:38:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	27 Oct 2020 14:38:33
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:31:42
User entered '167.6' cm	Rylea Gulick (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185194

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:56:56
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	27 Oct 2020 14:38:33
User entered '88.2' kg	Rylea Gulick (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '18:25'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185199

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered '13 Aug 2020 18:25'	(b) (4), (b) (6) System	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '37.2' C	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185202

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185203

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '94'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185204

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered 'bpm'	(b) (4), (b) (6) System	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185205

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '12'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185206

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185207

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '133'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185208

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered 'mmHg'	(b) (4), (b) (6) System	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185209

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '82'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:56:56
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered 'mmHg'	System	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185211

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:56:56
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:52:32
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4)	27 Oct 2020 14:38:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	27 Oct 2020 14:38:33
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, “ND” should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:31:42
User entered '167.6' cm	Rylea Gulick (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185212

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:56:56
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	27 Oct 2020 14:38:33
User entered '88.2' kg	Rylea Gulick (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User accepted default value 'Post-Dose (POSTDOSE)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185214

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 07:25:43
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'PER PROTOCOL, SUBJECT ONLY NEEDS TO WAIT 30 MINUTES AFTER VACCINATION BEFORE POST DOSE VITALS ARE TAKEN' (Site from System).	Rylea Gulick (b) (4)	14 Aug 2020 22:11:41
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	14 Aug 2020 22:11:18
User entered '19:50'	Rylea Gulick (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered '13 Aug 2020 19:50'	(b) (4), (b) (6) System	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185218

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '37.2' C	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered 'Oral (Oral)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185220

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185221

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '72'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185222

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered 'bpm'	(b) (4), (b) (6) System	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185223

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '14'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185225

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '125'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185226

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered 'mmHg'	(b) (4), (b) (6) System	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185227

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:19:46
User entered '77'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185228

US3042190
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:56:56
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered 'mmHg'	System	14 Aug 2020 22:11:18

FDA-CBER-2022-1614-0185229

US3042190
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 14:56:56
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:02
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:59

US3042190
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 14:56:56
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:02
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:11:59

US3042190
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:38
User closed query 'Per CDM please note as Screening and Visit 1 is done on the same date the Pregnancy test in Visit 1 screens to be changed as "NO".Kindly update ' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 10:37:18
Query 'Per CDM please note as Screening and Visit 1 is done on the same date the Pregnancy test in Visit 1 screens to be changed as "NO".Kindly update ' answered with 'DATA REMOVED' (Site from DM).	Rylea Gulick (b) (4)	02 Sep 2020 23:40:22
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	02 Sep 2020 23:40:18
User opened query 'Per CDM please note as Screening and Visit 1 is done on the same date the Pregnancy test in Visit 1 screens to be changed as "NO".Kindly update ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:24:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Aug 2020 22:12:29

FDA-CBER-2022-1614-0185232

US3042190
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:38
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:40:18
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:29

US3042190
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:38
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:40:18
User entered 'Urine (URINE)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:29

US3042190
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:38
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:40:18
User entered 'Negative (NEGATIVE)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:29

US3042190
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:38
User closed query 'Per CDM: Per CCGs, this question is to be answered and not left empty. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 08:04:45
Query 'Per CDM: Per CCGs, this question is to be answered and not left empty. Please update as appropriate. ' answered with 'updated' (Site from DM).	Jamie Thompson (b) (4)	01 Dec 2020 22:48:05
User entered 'No (N)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	01 Dec 2020 22:47:57
User opened query 'Per CDM: Per CCGs, this question is to be answered and not left empty. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:40:09
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	02 Sep 2020 23:40:18
User entered 'No (N)'	Rylea Gulick (b) (4)	14 Aug 2020 22:12:29

FDA-CBER-2022-1614-0185236

US3042190
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:38
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	02 Sep 2020 23:40:18
Query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed.The urine test time need not be filled in this field, this field is for FSH sample collection.As per the response the FSH collected is NO, kindly remove the date and time. Kindly correct.' canceled (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:24:38
User opened query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed.The urine test time need not be filled in this field, this field is for FSH sample collection.As per the response the FSH collected is NO, kindly remove the date and time. Kindly correct.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 04:09:30
User closed query 'Per CDM please note the FSH sample collected is No but the Collection date and time has been reported.Kindly confirm or correct accordingly' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 04:09:30
Query 'Per CDM please note the FSH sample collected is No but the Collection date and time has been reported.Kindly confirm or correct accordingly' answered with 'No FSH collected; time is for urine pregnancy test.' (Site from DM).	Jamie Thompson (b) (4)	29 Aug 2020 18:05:12
User opened query 'Per CDM please note the FSH sample collected is No but the Collection date and time has been reported.Kindly confirm or correct accordingly' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 09:16:58
User entered '13 Aug 2020'	Rylea Gulick (b) (4)	14 Aug 2020 22:12:29

US3042190
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:38
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:40:18
User entered '18:30'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:29

US3042190
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 14:56:56
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered empty.	System	02 Sep 2020 23:40:18
User entered '13 Aug 2020 18:30'	System	14 Aug 2020 22:12:29

FDA-CBER-2022-1614-0185239

US3042190
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:56:56
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:59
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:33

US3042190
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:56:56
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:59
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:33

US3042190
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:59
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185242

US3042190
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:56:56
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

US3042190
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:56:56
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:59
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:33

US3042190
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:56:56
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:59
User entered '19:16'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185245

US3042190
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:56:56
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered '13 Aug 2020 19:16'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

US3042190
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:56:56
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:59
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 00:32:33

US3042190
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:56:56
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:20:59
User entered 'ONCE'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185248

US3042190
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:56:56
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 00:32:33

US3042190
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:56:56
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:21:12
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:37

US3042190
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:56:56
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:21:12
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:37

US3042190
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:56:56
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:21:12
User entered '19:02'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:37

US3042190
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:56:56
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered '13 Aug 2020 19:02'	(b) (4), (b) (6) System	14 Aug 2020 22:12:37

FDA-CBER-2022-1614-0185253

US3042190
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 14:56:56
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:21:21
User entered '13 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:55

US3042190
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:56:56
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:55

FDA-CBER-2022-1614-0185255

US3042190
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:56:56
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:21:21
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:55

US3042190
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:56:56
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:21:21
User entered '18:52'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:55

FDA-CBER-2022-1614-0185257

US3042190
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:56:56
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered '13 Aug 2020 18:52'	(b) (4), (b) (6) System	14 Aug 2020 22:12:55

FDA-CBER-2022-1614-0185258

US3042190
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:56:56
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:55

FDA-CBER-2022-1614-0185259

US3042190
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:56:56
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:21:21
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:55

US3042190
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:56:56
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:21:21
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:55

FDA-CBER-2022-1614-0185261

US3042190
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:56:56
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered empty.	System	14 Aug 2020 22:12:55

FDA-CBER-2022-1614-0185262

US3042190
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 14:56:56
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 11:52:43
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:21:32
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:12:56

US3042190
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 14:56:56
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:43
User entered '1'	(b) (4), (b) (6) System	14 Aug 2020 22:12:56

FDA-CBER-2022-1614-0185264

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185265

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:39:09', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '74d5d116-3052-4c0f-9088-44f56b39ff2c'	System	14 Aug 2020 00:39:28
User entered 'Yes (Y)'	System	14 Aug 2020 00:39:28

FDA-CBER-2022-1614-0185266

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:39:16', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '74d5d116-3052-4c0f-9088-44f56b39ff2c'	System	14 Aug 2020 00:39:28
User entered '98.5'	System	14 Aug 2020 00:39:28

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:39:19', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '74d5d116-3052-4c0f-9088-44f56b39ff2c'	System	14 Aug 2020 00:39:28
User entered 'No (N)'	System	14 Aug 2020 00:39:28

FDA-CBER-2022-1614-0185268

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:39:24', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '74d5d116-3052-4c0f-9088-44f56b39ff2c'	System	14 Aug 2020 00:39:28
User entered '13 Aug 2020 19:39'	System	14 Aug 2020 00:39:28

FDA-CBER-2022-1614-0185269

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '13 Aug 2020 19:36'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185270

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '13 Aug 2020 22:06'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185271

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185272

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T09:59:49', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'e578f03e-b0e8-402f-ad37-073fe4ba30f6'	System	14 Aug 2020 15:00:08
User entered 'Yes (Y)'	System	14 Aug 2020 15:00:08

FDA-CBER-2022-1614-0185273

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T09:59:55', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'e578f03e-b0e8-402f-ad37-073fe4ba30f6'	System	14 Aug 2020 15:00:08
User entered '97.5'	System	14 Aug 2020 15:00:08

FDA-CBER-2022-1614-0185274

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T09:59:57', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'e578f03e-b0e8-402f-ad37-073fe4ba30f6'	System	14 Aug 2020 15:00:08
User entered 'No (N)'	System	14 Aug 2020 15:00:08

FDA-CBER-2022-1614-0185275

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:02', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'e578f03e-b0e8-402f-ad37-073fe4ba30f6'	System	14 Aug 2020 15:00:08
User entered '14 Aug 2020 10:00'	System	14 Aug 2020 15:00:08

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '13 Aug 2020 23:01'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185277

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185278

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 2'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185279

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:56:56
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:52:43', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'c05b97db-90e7-45b4-923e-e46109c95db5'	System	14 Aug 2020 23:52:59
User entered 'Yes (Y)'	System	14 Aug 2020 23:52:59

FDA-CBER-2022-1614-0185280

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:56:56
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:52:48', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'c05b97db-90e7-45b4-923e-e46109c95db5'	System	14 Aug 2020 23:52:59
User entered '97.2'	System	14 Aug 2020 23:52:59

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:56:56
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:52:50', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'c05b97db-90e7-45b4-923e-e46109c95db5'	System	14 Aug 2020 23:52:59
User entered 'No (N)'	System	14 Aug 2020 23:52:59

FDA-CBER-2022-1614-0185282

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:52:53', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'c05b97db-90e7-45b4-923e-e46109c95db5'	System	14 Aug 2020 23:52:59
User entered '14 Aug 2020 18:52'	System	14 Aug 2020 23:52:59

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185284

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185285

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 3'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185286

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:56:56
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:13:21', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '31d93345-d322-46c7-b1c3-5783f922d78f'	System	16 Aug 2020 01:13:34
User entered 'Yes (Y)'	System	16 Aug 2020 01:13:34

FDA-CBER-2022-1614-0185287

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:56:56
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:13:26', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '31d93345-d322-46c7-b1c3-5783f922d78f'	System	16 Aug 2020 01:13:34
User entered '98.0'	System	16 Aug 2020 01:13:34

FDA-CBER-2022-1614-0185288

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:56:56
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:13:29', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '31d93345-d322-46c7-b1c3-5783f922d78f'	System	16 Aug 2020 01:13:34
User entered 'No (N)'	System	16 Aug 2020 01:13:34

FDA-CBER-2022-1614-0185289

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:13:31', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '31d93345-d322-46c7-b1c3-5783f922d78f'	System	16 Aug 2020 01:13:34
User entered '15 Aug 2020 20:13'	System	16 Aug 2020 01:13:34

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185291

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185292

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 4'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185293

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:56:56
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:06', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '152539de-c82a-40fd-9c18-9a59e4248bec'	System	17 Aug 2020 00:13:21
User entered 'Yes (Y)'	System	17 Aug 2020 00:13:21

FDA-CBER-2022-1614-0185294

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:56:56
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:11', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '152539de-c82a-40fd-9c18-9a59e4248bec'	System	17 Aug 2020 00:13:21
User entered '98.5'	System	17 Aug 2020 00:13:21

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:56:56
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:13', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '152539de-c82a-40fd-9c18-9a59e4248bec'	System	17 Aug 2020 00:13:21
User entered 'No (N)'	System	17 Aug 2020 00:13:21

FDA-CBER-2022-1614-0185296

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:15', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '152539de-c82a-40fd-9c18-9a59e4248bec'	System	17 Aug 2020 00:13:21
User entered '16 Aug 2020 19:13'	System	17 Aug 2020 00:13:21

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185298

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185299

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 5'	System	14 Aug 2020 00:32:33

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:56:56
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:11', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'f6d92a36-c29f-4ade-8679-f92c1ef4eb07'	System	18 Aug 2020 12:06:22
User entered 'Yes (Y)'	System	18 Aug 2020 12:06:22

FDA-CBER-2022-1614-0185301

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:56:56
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:15', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'f6d92a36-c29f-4ade-8679-f92c1ef4eb07'	System	18 Aug 2020 12:06:22
User entered '97.1'	System	18 Aug 2020 12:06:22

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:56:56
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:17', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'f6d92a36-c29f-4ade-8679-f92c1ef4eb07'	System	18 Aug 2020 12:06:22
User entered 'No (N)'	System	18 Aug 2020 12:06:22

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:19', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'f6d92a36-c29f-4ade-8679-f92c1ef4eb07'	System	18 Aug 2020 12:06:22
User entered '18 Aug 2020 07:06'	System	18 Aug 2020 12:06:22

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185305

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185306

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 6'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185307

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:56:56
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:36:29', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '57209451-02ea-4ac8-9742-9854065b28e5'	System	19 Aug 2020 00:36:45
User entered 'Yes (Y)'	System	19 Aug 2020 00:36:45

FDA-CBER-2022-1614-0185308

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:56:56
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:36:33', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '57209451-02ea-4ac8-9742-9854065b28e5'	System	19 Aug 2020 00:36:45
User entered '97.1'	System	19 Aug 2020 00:36:45

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:56:56
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:36:37', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '57209451-02ea-4ac8-9742-9854065b28e5'	System	19 Aug 2020 00:36:45
User entered 'No (N)'	System	19 Aug 2020 00:36:45

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:36:39', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '57209451-02ea-4ac8-9742-9854065b28e5'	System	19 Aug 2020 00:36:45
User entered '18 Aug 2020 19:36'	System	19 Aug 2020 00:36:45

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185312

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185313

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 7'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185314

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:56:56
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:15', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '624ea63d-35ef-448b-b448-7e176cc66b06'	System	20 Aug 2020 00:58:28
User entered 'Yes (Y)'	System	20 Aug 2020 00:58:28

FDA-CBER-2022-1614-0185315

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:56:56
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:19', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '624ea63d-35ef-448b-b448-7e176cc66b06'	System	20 Aug 2020 00:58:28
User entered '97.6'	System	20 Aug 2020 00:58:28

FDA-CBER-2022-1614-0185316

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:56:56
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:21', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '624ea63d-35ef-448b-b448-7e176cc66b06'	System	20 Aug 2020 00:58:28
User entered 'No (N)'	System	20 Aug 2020 00:58:28

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:24', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '624ea63d-35ef-448b-b448-7e176cc66b06'	System	20 Aug 2020 00:58:28
User entered '19 Aug 2020 19:58'	System	20 Aug 2020 00:58:28

FDA-CBER-2022-1614-0185318

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185319

US3042190
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185320

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185321

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:39:32', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '4c3b8dd6-c893-44a7-8f3a-648b33960d92'	System	14 Aug 2020 00:39:59
User entered 'None (1)'	System	14 Aug 2020 00:39:59

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:39:43', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '4c3b8dd6-c893-44a7-8f3a-648b33960d92'	System	14 Aug 2020 00:39:59
User entered 'No (N)'	System	14 Aug 2020 00:39:59

FDA-CBER-2022-1614-0185323

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:39:47', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '4c3b8dd6-c893-44a7-8f3a-648b33960d92'	System	14 Aug 2020 00:39:59
User entered 'No (N)'	System	14 Aug 2020 00:39:59

FDA-CBER-2022-1614-0185324

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:39:53', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '4c3b8dd6-c893-44a7-8f3a-648b33960d92'	System	14 Aug 2020 00:39:59
User entered 'None (1)'	System	14 Aug 2020 00:39:59

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:39:56', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '4c3b8dd6-c893-44a7-8f3a-648b33960d92'	System	14 Aug 2020 00:39:59
User entered '13 Aug 2020 19:39'	System	14 Aug 2020 00:39:59

FDA-CBER-2022-1614-0185326

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '13 Aug 2020 19:36'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185327

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '13 Aug 2020 22:06'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185328

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 00:32:33

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:19', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '3d2a1de2-e939-454b-9cb9-a586347ec83d'	System	14 Aug 2020 15:00:41
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 15:00:41

FDA-CBER-2022-1614-0185330

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:23', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '3d2a1de2-e939-454b-9cb9-a586347ec83d'	System	14 Aug 2020 15:00:41
User entered 'No (N)'	System	14 Aug 2020 15:00:41

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:28', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '3d2a1de2-e939-454b-9cb9-a586347ec83d'	System	14 Aug 2020 15:00:41
User entered 'No (N)'	System	14 Aug 2020 15:00:41

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:34', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '3d2a1de2-e939-454b-9cb9-a586347ec83d'	System	14 Aug 2020 15:00:41
User entered 'None (1)'	System	14 Aug 2020 15:00:41

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:37', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '3d2a1de2-e939-454b-9cb9-a586347ec83d'	System	14 Aug 2020 15:00:41
User entered '14 Aug 2020 10:00'	System	14 Aug 2020 15:00:41

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '13 Aug 2020 23:01'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185335

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185336

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 2'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185337

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:56:56
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:53:12', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '633721e1-8c99-4156-9cec-a298cd19044c'	System	14 Aug 2020 23:53:49
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 23:53:49

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:56:56
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:53:23', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '633721e1-8c99-4156-9cec-a298cd19044c'	System	14 Aug 2020 23:53:49
User entered 'No (N)'	System	14 Aug 2020 23:53:49

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:56:56
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:53:36', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '633721e1-8c99-4156-9cec-a298cd19044c'	System	14 Aug 2020 23:53:49
User entered 'No (N)'	System	14 Aug 2020 23:53:49

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:56:56
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:53:43', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '633721e1-8c99-4156-9cec-a298cd19044c'	System	14 Aug 2020 23:53:49
User entered 'None (1)'	System	14 Aug 2020 23:53:49

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:53:46', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '633721e1-8c99-4156-9cec-a298cd19044c'	System	14 Aug 2020 23:53:49
User entered '14 Aug 2020 18:53'	System	14 Aug 2020 23:53:49

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185343

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185344

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 3'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185345

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:56:56
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:13:40', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '25d6f864-ea5c-4f1d-8018-c2c3e0170ca9'	System	16 Aug 2020 01:13:59
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 01:13:59

FDA-CBER-2022-1614-0185346

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:56:56
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:13:42', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '25d6f864-ea5c-4f1d-8018-c2c3e0170ca9'	System	16 Aug 2020 01:13:59
User entered 'No (N)'	System	16 Aug 2020 01:13:59

FDA-CBER-2022-1614-0185347

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:56:56
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:13:46', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '25d6f864-ea5c-4f1d-8018-c2c3e0170ca9'	System	16 Aug 2020 01:13:59
User entered 'No (N)'	System	16 Aug 2020 01:13:59

FDA-CBER-2022-1614-0185348

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:56:56
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:13:52', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '25d6f864-ea5c-4f1d-8018-c2c3e0170ca9'	System	16 Aug 2020 01:13:59
User entered 'None (1)'	System	16 Aug 2020 01:13:59

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:13:54', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '25d6f864-ea5c-4f1d-8018-c2c3e0170ca9'	System	16 Aug 2020 01:13:59
User entered '15 Aug 2020 20:13'	System	16 Aug 2020 01:13:59

FDA-CBER-2022-1614-0185350

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185351

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185352

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 4'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185353

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:56:56
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:19', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '3df5c442-cbbd-462d-a5a5-73d66c4cb0d4'	System	17 Aug 2020 00:13:32
User entered 'None (1)'	System	17 Aug 2020 00:13:32

FDA-CBER-2022-1614-0185354

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:56:56
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:22', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '3df5c442-cbbd-462d-a5a5-73d66c4cb0d4'	System	17 Aug 2020 00:13:32
User entered 'No (N)'	System	17 Aug 2020 00:13:32

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:56:56
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:23', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '3df5c442-cbbd-462d-a5a5-73d66c4cb0d4'	System	17 Aug 2020 00:13:32
User entered 'No (N)'	System	17 Aug 2020 00:13:32

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:56:56
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:26', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '3df5c442-cbbd-462d-a5a5-73d66c4cb0d4'	System	17 Aug 2020 00:13:32
User entered 'None (1)'	System	17 Aug 2020 00:13:32

FDA-CBER-2022-1614-0185357

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:28', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '3df5c442-cbbd-462d-a5a5-73d66c4cb0d4'	System	17 Aug 2020 00:13:32
User entered '16 Aug 2020 19:13'	System	17 Aug 2020 00:13:32

FDA-CBER-2022-1614-0185358

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185359

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185360

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 5'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185361

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:56:56
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:22', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '4b1c731e-e099-4ce3-8d1d-cbe32d5c46d4'	System	18 Aug 2020 12:06:33
User entered 'None (1)'	System	18 Aug 2020 12:06:33

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:56:56
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:25', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '4b1c731e-e099-4ce3-8d1d-cbe32d5c46d4'	System	18 Aug 2020 12:06:33
User entered 'No (N)'	System	18 Aug 2020 12:06:33

FDA-CBER-2022-1614-0185363

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:56:56
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:26', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '4b1c731e-e099-4ce3-8d1d-cbe32d5c46d4'	System	18 Aug 2020 12:06:33
User entered 'No (N)'	System	18 Aug 2020 12:06:33

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:56:56
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:27', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '4b1c731e-e099-4ce3-8d1d-cbe32d5c46d4'	System	18 Aug 2020 12:06:33
User entered 'None (1)'	System	18 Aug 2020 12:06:33

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:30', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '4b1c731e-e099-4ce3-8d1d-cbe32d5c46d4'	System	18 Aug 2020 12:06:33
User entered '18 Aug 2020 07:06'	System	18 Aug 2020 12:06:33

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185367

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185368

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 6'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185369

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:56:56
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:36:43', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'e52e4c40-8ea3-4509-923a-76a68fda464e'	System	19 Aug 2020 00:37:18
User entered 'None (1)'	System	19 Aug 2020 00:37:18

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:56:56
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:36:45', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'e52e4c40-8ea3-4509-923a-76a68fda464e'	System	19 Aug 2020 00:37:18
User entered 'No (N)'	System	19 Aug 2020 00:37:18

FDA-CBER-2022-1614-0185371

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:56:56
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:36:47', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'e52e4c40-8ea3-4509-923a-76a68fda464e'	System	19 Aug 2020 00:37:18
User entered 'No (N)'	System	19 Aug 2020 00:37:18

FDA-CBER-2022-1614-0185372

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:56:56
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:36:48', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'e52e4c40-8ea3-4509-923a-76a68fda464e'	System	19 Aug 2020 00:37:18
User entered 'None (1)'	System	19 Aug 2020 00:37:18

FDA-CBER-2022-1614-0185373

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:37:14', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'e52e4c40-8ea3-4509-923a-76a68fda464e'	System	19 Aug 2020 00:37:18
User entered '18 Aug 2020 19:37'	System	19 Aug 2020 00:37:18

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185375

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185376

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 7'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185377

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:56:56
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:27', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8d846374-8160-4bff-b3ae-c6da2f1892c5'	System	20 Aug 2020 00:58:41
User entered 'None (1)'	System	20 Aug 2020 00:58:41

FDA-CBER-2022-1614-0185378

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:56:56
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:29', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8d846374-8160-4bff-b3ae-c6da2f1892c5'	System	20 Aug 2020 00:58:41
User entered 'No (N)'	System	20 Aug 2020 00:58:41

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:56:56
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:30', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8d846374-8160-4bff-b3ae-c6da2f1892c5'	System	20 Aug 2020 00:58:41
User entered 'No (N)'	System	20 Aug 2020 00:58:41

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:56:56
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:32', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8d846374-8160-4bff-b3ae-c6da2f1892c5'	System	20 Aug 2020 00:58:41
User entered 'None (1)'	System	20 Aug 2020 00:58:41

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:56:56
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:36', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8d846374-8160-4bff-b3ae-c6da2f1892c5'	System	20 Aug 2020 00:58:41
User entered '19 Aug 2020 19:58'	System	20 Aug 2020 00:58:41

FDA-CBER-2022-1614-0185382

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185383

US3042190
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185384

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 00:32:33

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:40:04', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '6f75514c-28d9-4b91-a269-1f0a50630da2'	System	14 Aug 2020 00:40:26
User entered 'None (0)'	System	14 Aug 2020 00:40:26

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:40:07', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '6f75514c-28d9-4b91-a269-1f0a50630da2'	System	14 Aug 2020 00:40:26
User entered 'None (0)'	System	14 Aug 2020 00:40:26

FDA-CBER-2022-1614-0185387

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:40:10', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '6f75514c-28d9-4b91-a269-1f0a50630da2'	System	14 Aug 2020 00:40:26
User entered 'None (0)'	System	14 Aug 2020 00:40:26

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:40:12', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '6f75514c-28d9-4b91-a269-1f0a50630da2'	System	14 Aug 2020 00:40:26
User entered 'None (0)'	System	14 Aug 2020 00:40:26

FDA-CBER-2022-1614-0185389

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:40:14', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '6f75514c-28d9-4b91-a269-1f0a50630da2'	System	14 Aug 2020 00:40:26
User entered 'None (0)'	System	14 Aug 2020 00:40:26

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:40:16', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '6f75514c-28d9-4b91-a269-1f0a50630da2'	System	14 Aug 2020 00:40:26
User entered 'None (0)'	System	14 Aug 2020 00:40:26

FDA-CBER-2022-1614-0185391

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:40:21', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '6f75514c-28d9-4b91-a269-1f0a50630da2'	System	14 Aug 2020 00:40:26
User entered 'No (N)'	System	14 Aug 2020 00:40:26

FDA-CBER-2022-1614-0185392

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-13T19:40:23', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '6f75514c-28d9-4b91-a269-1f0a50630da2'	System	14 Aug 2020 00:40:26
User entered '13 Aug 2020 19:40'	System	14 Aug 2020 00:40:26

FDA-CBER-2022-1614-0185393

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '13 Aug 2020 19:36'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185394

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '13 Aug 2020 22:06'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185395

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 00:32:33

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:41', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'c58de41e-8fc6-41a1-b1e2-b13aaedba773'	System	14 Aug 2020 15:01:04
User entered 'None (0)'	System	14 Aug 2020 15:01:04

FDA-CBER-2022-1614-0185397

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:43', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'c58de41e-8fc6-41a1-b1e2-b13aaedba773'	System	14 Aug 2020 15:01:04
User entered 'None (0)'	System	14 Aug 2020 15:01:04

FDA-CBER-2022-1614-0185398

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:46', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'c58de41e-8fc6-41a1-b1e2-b13aaedba773'	System	14 Aug 2020 15:01:04
User entered 'None (0)'	System	14 Aug 2020 15:01:04

FDA-CBER-2022-1614-0185399

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:48', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'c58de41e-8fc6-41a1-b1e2-b13aaedba773'	System	14 Aug 2020 15:01:04
User entered 'None (0)'	System	14 Aug 2020 15:01:04

FDA-CBER-2022-1614-0185400

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:50', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'c58de41e-8fc6-41a1-b1e2-b13aaedba773'	System	14 Aug 2020 15:01:04
User entered 'None (0)'	System	14 Aug 2020 15:01:04

FDA-CBER-2022-1614-0185401

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:52', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'c58de41e-8fc6-41a1-b1e2-b13aaedba773'	System	14 Aug 2020 15:01:04
User entered 'None (0)'	System	14 Aug 2020 15:01:04

FDA-CBER-2022-1614-0185402

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:56', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'c58de41e-8fc6-41a1-b1e2-b13aaedba773'	System	14 Aug 2020 15:01:04
User entered 'No (N)'	System	14 Aug 2020 15:01:04

FDA-CBER-2022-1614-0185403

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T10:00:58', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: 'c58de41e-8fc6-41a1-b1e2-b13aaedba773'	System	14 Aug 2020 15:01:04
User entered '14 Aug 2020 10:00'	System	14 Aug 2020 15:01:04

FDA-CBER-2022-1614-0185404

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '13 Aug 2020 23:01'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185405

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185406

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 2'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185407

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:56:56
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:53:50', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8681f9f7-e3d8-47ba-a1b1-3b5219fc6249'	System	14 Aug 2020 23:54:15
User entered 'None (0)'	System	14 Aug 2020 23:54:15

FDA-CBER-2022-1614-0185408

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:56:56
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:53:52', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8681f9f7-e3d8-47ba-a1b1-3b5219fc6249'	System	14 Aug 2020 23:54:15
User entered 'None (0)'	System	14 Aug 2020 23:54:15

FDA-CBER-2022-1614-0185409

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:56:56
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:53:54', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8681f9f7-e3d8-47ba-a1b1-3b5219fc6249'	System	14 Aug 2020 23:54:15
User entered 'None (0)'	System	14 Aug 2020 23:54:15

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:56:56
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:53:56', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8681f9f7-e3d8-47ba-a1b1-3b5219fc6249'	System	14 Aug 2020 23:54:15
User entered 'None (0)'	System	14 Aug 2020 23:54:15

FDA-CBER-2022-1614-0185411

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:56:56
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:53:58', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8681f9f7-e3d8-47ba-a1b1-3b5219fc6249'	System	14 Aug 2020 23:54:15
User entered 'None (0)'	System	14 Aug 2020 23:54:15

FDA-CBER-2022-1614-0185412

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:56:56
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:53:59', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8681f9f7-e3d8-47ba-a1b1-3b5219fc6249'	System	14 Aug 2020 23:54:15
User entered 'None (0)'	System	14 Aug 2020 23:54:15

FDA-CBER-2022-1614-0185413

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:54:08', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8681f9f7-e3d8-47ba-a1b1-3b5219fc6249'	System	14 Aug 2020 23:54:15
User entered 'No (N)'	System	14 Aug 2020 23:54:15

FDA-CBER-2022-1614-0185414

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:56:56
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-14T18:54:11', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '8681f9f7-e3d8-47ba-a1b1-3b5219fc6249'	System	14 Aug 2020 23:54:15
User entered '14 Aug 2020 18:54'	System	14 Aug 2020 23:54:15

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185416

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185417

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 3'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185418

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:13:58', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '93e766ce-9380-4a05-8c3a-2852078950de'	System	16 Aug 2020 01:14:12
User entered 'None (0)'	System	16 Aug 2020 01:14:12

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:13:59', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '93e766ce-9380-4a05-8c3a-2852078950de'	System	16 Aug 2020 01:14:12
User entered 'None (0)'	System	16 Aug 2020 01:14:12

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:14:01', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '93e766ce-9380-4a05-8c3a-2852078950de'	System	16 Aug 2020 01:14:12
User entered 'None (0)'	System	16 Aug 2020 01:14:12

FDA-CBER-2022-1614-0185421

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:14:02', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '93e766ce-9380-4a05-8c3a-2852078950de'	System	16 Aug 2020 01:14:12
User entered 'None (0)'	System	16 Aug 2020 01:14:12

FDA-CBER-2022-1614-0185422

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:14:03', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '93e766ce-9380-4a05-8c3a-2852078950de'	System	16 Aug 2020 01:14:12
User entered 'None (0)'	System	16 Aug 2020 01:14:12

FDA-CBER-2022-1614-0185423

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:14:05', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '93e766ce-9380-4a05-8c3a-2852078950de'	System	16 Aug 2020 01:14:12
User entered 'None (0)'	System	16 Aug 2020 01:14:12

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:14:06', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '93e766ce-9380-4a05-8c3a-2852078950de'	System	16 Aug 2020 01:14:12
User entered 'No (N)'	System	16 Aug 2020 01:14:12

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-15T20:14:08', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '93e766ce-9380-4a05-8c3a-2852078950de'	System	16 Aug 2020 01:14:12
User entered '15 Aug 2020 20:14'	System	16 Aug 2020 01:14:12

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185427

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185428

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 4'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185429

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:56:56
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:31', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '21bec021-ecf1-48f9-8a60-92e12e0259d3'	System	17 Aug 2020 00:13:51
User entered 'None (0)'	System	17 Aug 2020 00:13:51

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:56:56
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:33', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '21bec021-ecf1-48f9-8a60-92e12e0259d3'	System	17 Aug 2020 00:13:51
User entered 'None (0)'	System	17 Aug 2020 00:13:51

FDA-CBER-2022-1614-0185431

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:56:56
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:34', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '21bec021-ecf1-48f9-8a60-92e12e0259d3'	System	17 Aug 2020 00:13:51
User entered 'None (0)'	System	17 Aug 2020 00:13:51

FDA-CBER-2022-1614-0185432

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:56:56
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:35', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '21bec021-ecf1-48f9-8a60-92e12e0259d3'	System	17 Aug 2020 00:13:51
User entered 'None (0)'	System	17 Aug 2020 00:13:51

FDA-CBER-2022-1614-0185433

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:56:56
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:37', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '21bec021-ecf1-48f9-8a60-92e12e0259d3'	System	17 Aug 2020 00:13:51
User entered 'None (0)'	System	17 Aug 2020 00:13:51

FDA-CBER-2022-1614-0185434

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:56:56
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:38', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '21bec021-ecf1-48f9-8a60-92e12e0259d3'	System	17 Aug 2020 00:13:51
User entered 'None (0)'	System	17 Aug 2020 00:13:51

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:45', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '21bec021-ecf1-48f9-8a60-92e12e0259d3'	System	17 Aug 2020 00:13:51
User entered 'No (N)'	System	17 Aug 2020 00:13:51

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:56:56
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-16T19:13:47', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '21bec021-ecf1-48f9-8a60-92e12e0259d3'	System	17 Aug 2020 00:13:51
User entered '16 Aug 2020 19:13'	System	17 Aug 2020 00:13:51

FDA-CBER-2022-1614-0185437

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185438

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185439

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 5'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185440

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:33', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '030d0954-6e86-40d7-ad95-8914dcde4681'	System	18 Aug 2020 12:06:48
User entered 'None (0)'	System	18 Aug 2020 12:06:48

FDA-CBER-2022-1614-0185441

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:35', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '030d0954-6e86-40d7-ad95-8914dcde4681'	System	18 Aug 2020 12:06:48
User entered 'None (0)'	System	18 Aug 2020 12:06:48

FDA-CBER-2022-1614-0185442

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:36', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '030d0954-6e86-40d7-ad95-8914dcde4681'	System	18 Aug 2020 12:06:48
User entered 'None (0)'	System	18 Aug 2020 12:06:48

FDA-CBER-2022-1614-0185443

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:38', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '030d0954-6e86-40d7-ad95-8914dcde4681'	System	18 Aug 2020 12:06:48
User entered 'None (0)'	System	18 Aug 2020 12:06:48

FDA-CBER-2022-1614-0185444

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:39', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '030d0954-6e86-40d7-ad95-8914dcde4681'	System	18 Aug 2020 12:06:48
User entered 'None (0)'	System	18 Aug 2020 12:06:48

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:40', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '030d0954-6e86-40d7-ad95-8914dcde4681'	System	18 Aug 2020 12:06:48
User entered 'None (0)'	System	18 Aug 2020 12:06:48

FDA-CBER-2022-1614-0185446

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:42', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '030d0954-6e86-40d7-ad95-8914dcde4681'	System	18 Aug 2020 12:06:48
User entered 'No (N)'	System	18 Aug 2020 12:06:48

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T07:06:44', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '030d0954-6e86-40d7-ad95-8914dcde4681'	System	18 Aug 2020 12:06:48
User entered '18 Aug 2020 07:06'	System	18 Aug 2020 12:06:48

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185449

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185450

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 6'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185451

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:56:56
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:37:21', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '47b8761a-b12e-4672-88ef-ef253f46a178'	System	19 Aug 2020 00:37:38
User entered 'None (0)'	System	19 Aug 2020 00:37:38

FDA-CBER-2022-1614-0185452

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:56:56
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:37:22', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '47b8761a-b12e-4672-88ef-ef253f46a178'	System	19 Aug 2020 00:37:38
User entered 'None (0)'	System	19 Aug 2020 00:37:38

FDA-CBER-2022-1614-0185453

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:56:56
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:37:23', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '47b8761a-b12e-4672-88ef-ef253f46a178'	System	19 Aug 2020 00:37:38
User entered 'None (0)'	System	19 Aug 2020 00:37:38

FDA-CBER-2022-1614-0185454

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:56:56
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:37:25', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '47b8761a-b12e-4672-88ef-ef253f46a178'	System	19 Aug 2020 00:37:38
User entered 'None (0)'	System	19 Aug 2020 00:37:38

FDA-CBER-2022-1614-0185455

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:56:56
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:37:26', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '47b8761a-b12e-4672-88ef-ef253f46a178'	System	19 Aug 2020 00:37:38
User entered 'None (0)'	System	19 Aug 2020 00:37:38

FDA-CBER-2022-1614-0185456

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:56:56
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:37:27', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '47b8761a-b12e-4672-88ef-ef253f46a178'	System	19 Aug 2020 00:37:38
User entered 'None (0)'	System	19 Aug 2020 00:37:38

FDA-CBER-2022-1614-0185457

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:37:29', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '47b8761a-b12e-4672-88ef-ef253f46a178'	System	19 Aug 2020 00:37:38
User entered 'No (N)'	System	19 Aug 2020 00:37:38

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:56:56
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-18T19:37:31', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '47b8761a-b12e-4672-88ef-ef253f46a178'	System	19 Aug 2020 00:37:38
User entered '18 Aug 2020 19:37'	System	19 Aug 2020 00:37:38

FDA-CBER-2022-1614-0185459

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185460

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185461

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
Data entry locked.	System	14 Aug 2020 00:32:33
User entered 'Day 7'	System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185462

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:39', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '79b93a32-df7b-49d2-8f1f-51332cee1bd1'	System	20 Aug 2020 00:58:53
User entered 'None (0)'	System	20 Aug 2020 00:58:53

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:40', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '79b93a32-df7b-49d2-8f1f-51332cee1bd1'	System	20 Aug 2020 00:58:53
User entered 'None (0)'	System	20 Aug 2020 00:58:53

FDA-CBER-2022-1614-0185464

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:42', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '79b93a32-df7b-49d2-8f1f-51332cee1bd1'	System	20 Aug 2020 00:58:53
User entered 'None (0)'	System	20 Aug 2020 00:58:53

FDA-CBER-2022-1614-0185465

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:43', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '79b93a32-df7b-49d2-8f1f-51332cee1bd1'	System	20 Aug 2020 00:58:53
User entered 'None (0)'	System	20 Aug 2020 00:58:53

FDA-CBER-2022-1614-0185466

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:44', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '79b93a32-df7b-49d2-8f1f-51332cee1bd1'	System	20 Aug 2020 00:58:53
User entered 'None (0)'	System	20 Aug 2020 00:58:53

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:45', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '79b93a32-df7b-49d2-8f1f-51332cee1bd1'	System	20 Aug 2020 00:58:53
User entered 'None (0)'	System	20 Aug 2020 00:58:53

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56
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) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:47', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '79b93a32-df7b-49d2-8f1f-51332cee1bd1'	System	20 Aug 2020 00:58:53
User entered 'No (N)'	System	20 Aug 2020 00:58:53

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d952ce5b69039f6d)', Time: '2020-08-19T19:58:49', User OID: 'PatientReportedOutcome (US3042190)', ODM File OID: '79b93a32-df7b-49d2-8f1f-51332cee1bd1'	System	20 Aug 2020 00:58:53
User entered '19 Aug 2020 19:58'	System	20 Aug 2020 00:58:53

FDA-CBER-2022-1614-0185470

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185471

US3042190
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:56:56
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:19
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 00:32:33

FDA-CBER-2022-1614-0185472

US3042190
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:56:56
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 03:28:52
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:12
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 22:22:00

US3042190
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:56:56
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 03:28:52
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:12
User entered '20 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 22:22:00

US3042190
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:56:56
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 03:28:52
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:12
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 22:22:00

FDA-CBER-2022-1614-0185475

US3042190
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:56:56
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 03:28:52
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:12
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 22:22:00

US3042190
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:56:56
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 03:28:52
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:22
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 22:22:01

US3042190
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:56:56
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:52
User entered '1'	(b) (4), (b) (6) System	20 Aug 2020 22:22:01

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US3042190
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:56:56
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 03:28:52
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:33
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 22:13:53

US3042190
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:56:56
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 03:28:52
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:33
User entered '27 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 22:13:53

US3042190
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:56:56
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 03:28:52
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:33
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 22:13:53

US3042190
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:56:56
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 03:28:52
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:33
User entered empty.	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 22:13:53

US3042190
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:56:56
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 03:28:52
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:40
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 22:13:56

US3042190
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:56:56
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:52
User entered '1'	(b) (4), (b) (6) System	03 Sep 2020 22:13:56

FDA-CBER-2022-1614-0185484

US3042190
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:56:56
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:58
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 22:14:04

US3042190
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:56:56
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:58
User entered '03 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 22:14:04

US3042190
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:56:56
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:58
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 22:14:04

US3042190
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:56:56
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:22:58
User entered empty.	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 22:14:04

FDA-CBER-2022-1614-0185488

US3042190
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:56:56
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:25:09
User closed query 'Per CDM, re-query: If the participant is not continuing to the next visit, then please update this field accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 06:56:20
Query 'Per CDM, re-query: If the participant is not continuing to the next visit, then please update this field accordingly. Thank you. ' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:14
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:09
User closed query 'Per CDM: Is the participant continuing to the next visit? = Yes; however, End of study form is completed. If Visit 2 Day 29 occurred, then complete the forms in Visit 2 Day 29 folder as appropriate. Else, update this field accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:16:04
User opened query 'Per CDM, re-query: If the participant is not continuing to the next visit, then please update this field accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:16:03
Query 'Per CDM: Is the participant continuing to the next visit? = Yes; however, End of study form is completed. If Visit 2 Day 29 occurred, then complete the forms in Visit 2 Day 29 folder as appropriate. Else, update this field accordingly. Thank you.' answered with 'Patient called in SAE AFTER this phone call was completed. ' (Site from DM).	Jamie Thompson (b) (4) (b) (4)	23 Nov 2020 22:22:02
Query 'Per CDM: Is the participant continuing to the next visit? = Yes; however, End of study form is completed. Please review and update this field accordingly, else clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:45:19

US3042190
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:56:56
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User opened query 'Per CDM: Is the participant continuing to the next visit? = Yes; however, End of study form is completed. If Visit 2 Day 29 occurred, then complete the forms in Visit 2 Day 29 folder as appropriate. Else, update this field accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:45:16
User opened query 'Per CDM: Is the participant continuing to the next visit? = Yes; however, End of study form is completed. Please review and update this field accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:26:25
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 22:14:06

FDA-CBER-2022-1614-0185490

US3042190
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:56:56
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 07:34:32
User entered empty.	System	02 Dec 2020 17:21:09
User entered '1'	System	03 Sep 2020 22:14:06

US3042190
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 14:56:56
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
User closed query 'Per CDM: Per Dosing Discontinuation form Primary reason for dosing discontinuation = SAE 1; however on the AE page Action taken with investigational product = None. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:57:25
Query 'Per CDM: Per Dosing Discontinuation form Primary reason for dosing discontinuation = SAE 1; however on the AE page Action taken with investigational product = None. Please review and update as appropriate. ' answered with 'entry updated ' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 14:58:56
User opened query 'Per CDM: Per Dosing Discontinuation form Primary reason for dosing discontinuation = SAE 1; however on the AE page Action taken with investigational product = None. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 12:47:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:36:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:21:20
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 22:14:13

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:46:16
User entered 'USA-US052-2020-mRNA-1273-P301000003'	System	11 Sep 2020 15:42:00
User entered 'New'	(b) (4), (b) (6)	11 Sep 2020 15:42:00

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:49:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: 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)	16 Sep 2020 11:25:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 11:25:35
Data point term sent to Coder	System	10 Sep 2020 18:52:14
User entered 'Multiple Pulmonary Emboli'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered 'No (N)'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered 'No (N)'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:03:49
User closed query 'PV Query: Please confirm event onset date (reported as 09 Sep 2020). It has been reported the subject began to experience event symptoms on 08 Sep 2020. ' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 13:48:19
Query 'PV Query: Please confirm event onset date (reported as 09 Sep 2020). It has been reported the subject began to experience event symptoms on 08 Sep 2020. ' answered with 'this date is correct.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 16:33:21
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 16:33:15
User entered '09 Sep 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 16:33:15
User opened query 'PV Query: Please confirm event onset date (reported as 09 Sep 2020). It has been reported the subject began to experience event symptoms on 08 Sep 2020. ' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 14:09:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered '9 Sep 2020'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
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	10 Sep 2020 18:52:54
User entered empty; reason for change Data Entry Error	Jamie Thompson (b) (4)	10 Sep 2020 18:52:54
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	10 Sep 2020 18:51:57
User entered '08:00'	Jamie Thompson (b) (4)	10 Sep 2020 18:51:57

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US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered empty.	System	10 Sep 2020 18:52:54
User entered '9 Sep 2020 08:00'	System	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Oct 2020 19:11:59
User entered 'No (N)' reason for change: Data Entry Error	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 19:11:59
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Oct 2020 19:11:43
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	02 Oct 2020 19:11:43
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	02 Oct 2020 19:11:43
User entered '10 Sep 2020' reason for change: Data Entry Error	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 19:11:43
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	02 Oct 2020 18:35:50
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 14:27:06
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)	25 Sep 2020 14:25:13
User entered empty.	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered empty.	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 16:22:45
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)	16 Sep 2020 18:05:17
User entered empty.	System	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 17:33:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 17:33:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 17:33:11
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 18:51:57
User entered empty.	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

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US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Sep 2020 17:33:11
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	16 Sep 2020 17:33:11
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	10 Sep 2020 18:51:57
User entered '1'	Jamie Thompson (b) (4)	10 Sep 2020 18:51:57

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and consider selecting serious criterion of medically important event.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 16:10:53
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and consider selecting serious criterion of medically important event.' answered with 'SUBJECT WAS HOSPITALIZED OVERNIGHT' (Site from Safety).	Rylea Gulick (b) (4)	02 Nov 2020 17:43:08
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and consider selecting serious criterion of medically important event.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 13:25:13
User entered '9 Sep 2020'	Jamie Thompson (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered '10 Sep 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	16 Sep 2020 17:33:11
User entered empty.	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered 'No (N)'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered empty.	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

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Folder: Adverse Events
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Generated On: 09 Jun 2021 14:56:56
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User closed query 'PV Query: Please provide causality assessment for the event. Correct response should be Not related or Related.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 16:10:57
Query 'PV Query: Please provide causality assessment for the event. Correct response should be Not related or Related.' answered with 'ENTRY UPDATED' (Site from Safety).	Rylea Gulick (b) (4)	02 Nov 2020 17:43:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	02 Nov 2020 17:43:33
User opened query 'PV Query: Please provide causality assessment for the event. Correct response should be Not related or Related.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 13:26:32
Query 'Safety Medical Query: Please provide causality assessment for the event. Correct response should be Not related or Related.' canceled (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 13:26:25
User opened query 'Safety Medical Query: Please provide causality assessment for the event. Correct response should be Not related or Related.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 13:26:06
User closed 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 Sep 2020 00:04:15
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	18 Sep 2020 00:04:15
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 Sep 2020 00:03:17
User entered 'Not Related (NOT RELATED)'	Jamie Thompson (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered 'Not Related (NOT RELATED)'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:28:30
DataPoint Un-verified.	Rylea Gulick (b) (4)	11 Dec 2020 14:58:48
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	11 Dec 2020 14:58:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User closed query 'PV Query: Please provide action taken with study drug, along with dechallenge and rechallenge for event of multiple pulmonary emboli.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 15:51:47
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	18 Sep 2020 00:04:15
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	18 Sep 2020 00:04:15
User entered 'None (NONE)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	18 Sep 2020 00:04:15
Query 'PV Query: Please provide action taken with study drug, along with dechallenge and rechallenge for event of multiple pulmonary emboli.' answered with 'Patient was withdrawn from the study' (Site from Safety).	Jamie Thompson (b) (4)	18 Sep 2020 00:03:50
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 00:03:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 00:03:17

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Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	18 Sep 2020 00:03:17
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:03:17
User opened query 'PV Query: Please provide action taken with study drug, along with dechallenge and rechallenge for event of multiple pulmonary emboli.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:06:10
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 18:51:57
User entered empty.	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 16:22:50
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 'data added' (Site from Safety).	Meagan Miller (b) (4)	02 Oct 2020 18:36:07
User entered '0' reason for change: Data Entry Error	Meagan Miller (b) (4)	02 Oct 2020 18:35:50
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Sep 2020 00:03:17
User entered '1' reason for change: Data Entry Error	Jamie Thompson (b) (4)	18 Sep 2020 00:03:17
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)	16 Sep 2020 18:06:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Sep 2020 18:51:57
User entered '0'	Jamie Thompson (b) (4)	10 Sep 2020 18:51:57

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Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User closed query 'PV Query: Please confirm if the "new oral contraception pill" should be considered co-suspect medication. If yes, please provide the name of the medication.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:26:26
Query 'PV Query: Please confirm if the "new oral contraception pill" should be considered co-suspect medication. If yes, please provide the name of the medication.' answered with 'will confirm when pi assess' (Site from Safety).	Meagan Miller (b) (4)	02 Oct 2020 18:36:58
User entered '1' reason for change: Data Entry Error	Meagan Miller (b) (4)	02 Oct 2020 18:35:50
User opened query 'PV Query: Please confirm if the "new oral contraception pill" should be considered co-suspect medication. If yes, please provide the name of the medication.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:07:01
User entered '0'	Jamie Thompson (b) (4)	10 Sep 2020 18:51:57

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US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered '0'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

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Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
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) (6)	05 Oct 2020 12:26:27
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 added' (Site from Safety).	Meagan Miller (b) (4)	02 Oct 2020 18:37:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Meagan Miller (b) (4)	02 Oct 2020 18:35:50
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)	25 Sep 2020 14:25:32
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) (6)	18 Sep 2020 15:51:56
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 'Patient is out of hospital and being followed up by PCP' (Site from Safety).	Jamie Thompson (b) (4)	18 Sep 2020 00:04:42
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 00:03:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 00:03:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	18 Sep 2020 00:03:17

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Outcome

Audit	User	Time (GMT)
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)	16 Sep 2020 18:05:48
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 18:51:57
User entered empty.	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

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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) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User entered empty.	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

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Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 22:49:24
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 22:49:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'labs sent with discharge summary' (Site from Safety).	Jamie Thompson (b) (4)	14 Dec 2020 19:07:42
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records emailed; please let me know if not received. ' (Site from Safety).	Jamie Thompson (b) (4)	14 Dec 2020 19:07:04
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 22:31:23
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 22:30:55
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:04
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:06:09

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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:06:06
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'awaiting from hosptial' (Site from Safety).	Jamie Thompson (b) (4) (b) (4)	04 Nov 2020 21:14:03
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'awaiting from hospital' (Site from Safety).	Jamie Thompson (b) (4) (b) (4)	04 Nov 2020 21:13:53
User closed query 'PV Query: Thank you for confirming as co-suspect medication. Please provide the name of the "new oral contraception pill" once available.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 16:11:04
Query 'PV Query: Thank you for confirming as co-suspect medication. Please provide the name of the "new oral contraception pill" once available.' answered with 'WILL BE PROVIDED ONCE AVAILABLE' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	02 Nov 2020 17:44:23
User opened query 'PV Query: Thank you for confirming as co-suspect medication. Please provide the name of the "new oral contraception pill" once available.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 13:25:05
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 13:24:36
User closed query 'PV Query: Please confirm if the "new oral contraception pill" should be considered co-suspect medication. If yes, please provide the name of the medication.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 14:39:43
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 14:39:29

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Narrative

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE NARRATIVE: PATIENT STATES STARTED NEW ORAL CONTRACEPTION PILL LAST WEEK AND BEGAN EXPERIENCING BACK PAIN. However, these information is not captured in the appropriate eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:10:12
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'RELEVANT LAB AND DIAGNOSTIC TEST RESULTS WILL BE PROVIDED WHEN AVAILABLE' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:36:11
Query 'PV Query: Please confirm if the "new oral contraception pill" should be considered co-suspect medication. If yes, please provide the name of the medication.' answered with 'NEW ORAL CONTRACEPTION PILL IS CONSIDERED A CO-SUSPECT MEDICATION. NAME OF MEDICATION IS STILL BEING OBTAINED.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 16:35:45
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:14:04
User opened query 'PV Query: Please confirm if the "new oral contraception pill" should be considered co-suspect medication. If yes, please provide the name of the medication.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:13:48
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:13:40
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:26:37

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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:26:32
Query 'Per DM CLR: SAE NARRATIVE: PATIENT STATES STARTED NEW ORAL CONTRACEPTION PILL LAST WEEK AND BEGAN EXPERIENCING BACK PAIN. However, these information is not captured in the appropriate eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'will update ' (Site from DM).	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:38:21
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'will send when med records are available ' (Site from Safety).	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:38:08
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'will send when med records are available ' (Site from Safety).	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:38:03
User opened query 'Per DM CLR: SAE NARRATIVE: PATIENT STATES STARTED NEW ORAL CONTRACEPTION PILL LAST WEEK AND BEGAN EXPERIENCING BACK PAIN. However, these information is not captured in the appropriate eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 21:23:50
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 14:29:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:06:21

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Narrative

Audit	User	Time (GMT)
User entered 'Patient called to report admittance into the hospital for multiple pulmonary emobli. Patient states started new oral contraception pill last week and began experiencing back pain. Patient went to PCP for consult and was admitted to hospital.'	Jamie Thompson (b) (4) (b) (4)	10 Sep 2020 18:51:57

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '1'	System	10 Sep 2020 18:51:57

FDA-CBER-2022-1614-0185532

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '1'	System	10 Sep 2020 18:51:57

FDA-CBER-2022-1614-0185533

US3042190
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:56:56
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '0'	System	10 Sep 2020 18:51:57

FDA-CBER-2022-1614-0185534

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 09 Jun 2021 14:56:56
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:49:49
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:10

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE HYDROCHLORIDE, PRODUCTSYNONYM: HYDROXIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:08
Data point term sent to Coder	System	14 Aug 2020 22:14:31
User entered 'HYDROXIZINE'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'ANXIETY'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '25'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 17:53:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4)	14 Aug 2020 22:13:47
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	14 Aug 2020 22:13:35
User entered 'UN UNK 2019'	Rylea Gulick (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User entered empty.	System	14 Aug 2020 22:13:35

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User entered empty.	System	14 Aug 2020 22:13:35

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US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:56:56
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User entered empty.	System	14 Aug 2020 22:13:35

FDA-CBER-2022-1614-0185553

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:21:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:21:48
Data point term sent to Coder	System	14 Aug 2020 22:14:31
User entered 'LEXAPRO'	Rylea Gulick (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

FDA-CBER-2022-1614-0185555

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'ANXIETY'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '30'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 17:53:24
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.' answered with 'ALL MEDICATION ONGING' (Site from System).	Rylea Gulick (b) (4)	14 Aug 2020 22:14:19
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	14 Aug 2020 22:14:09
User entered 'UN UNK 2019'	Rylea Gulick (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User entered '1'	System	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User entered '1'	System	14 Aug 2020 22:14:09

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:56:56
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User entered '804 (804)'	System	14 Aug 2020 22:14:09

FDA-CBER-2022-1614-0185571

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:42:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:42:49
Data point term sent to Coder	System	02 Oct 2020 18:41:38
User entered 'mirena'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'Yes (Y)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'contraception'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '52'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'IU (IU)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

FDA-CBER-2022-1614-0185577

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'other (OTHER)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'Q5years'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'Vaginal (VAGINAL)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'un Jun 2020'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '0'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

FDA-CBER-2022-1614-0185583

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'No (N)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '09 Sep 2020'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:46:11
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'No (N)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:41:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:11
User entered empty.	(b) (4), (b) (6) System	02 Oct 2020 18:41:21

FDA-CBER-2022-1614-0185587

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:11
User entered empty.	(b) (4), (b) (6) System	02 Oct 2020 18:41:21

FDA-CBER-2022-1614-0185588

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:56:56
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:11
User entered empty.	(b) (4), (b) (6) System	02 Oct 2020 18:41:21

FDA-CBER-2022-1614-0185589

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 18:43:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 18:43:51
Data point term sent to Coder	System	02 Oct 2020 18:42:39
User entered 'eliquis'	Meagan Miller (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'No (N)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'multiple pulmonary emboli'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '5'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'mg (mg)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'once daily (QD)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'Oral (ORAL)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '10 Sep 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:22:11
User entered '09 Sep 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:21:44
User entered '10 Sep 2020'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '0'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
User closed query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or provide clarification for continued use of the medication. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:14:48
Query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or provide clarification for continued use of the medication. Thank you. ' answered with 'UNSURE IF MEDICATION IS STILL ONGOING OR NOT, AS SUBJECT WAS EARLY TERMINATED FROM STUDY DUE TO MULTIPLE PULMONARY EMBOLI.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	19 Jan 2021 22:57:34
User closed query 'Per DM CLR: RQ: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:53:01
User opened query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or provide clarification for continued use of the medication. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:52:59
Query 'Per DM CLR: RQ: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'CON MED WILL BE REVIEWED AND UPDATED AS NECESSARY' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 16:11:44
User opened query 'Per DM CLR: RQ: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 04:34:29
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:32:36

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'MEDICATION IS STILL ONGOING' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:22:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:22:11
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:21:44
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:55:06
User entered 'Yes (Y)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:22:11
User entered '10 Sep 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:21:44
User entered empty.	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

FDA-CBER-2022-1614-0185604

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'No (N)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User entered '1'	System	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User entered '1'	System	02 Oct 2020 18:42:21

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:56:56
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User entered '804 (804)'	System	02 Oct 2020 18:42:21

FDA-CBER-2022-1614-0185608

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 05:13:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 05:13:53
Data point term sent to Coder	System	02 Oct 2020 18:44:45
User entered 'progesterone'	Meagan Miller (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'No (N)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
User closed query 'Per DM CLR: Please review Indication and please note that this medication is not typically used as treatment for the indicated condition. Please review and update applicable details as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:59:40
Query 'Per DM CLR: Please review Indication and please note that this medication is not typically used as treatment for the indicated condition. Please review and update applicable details as appropriate or provide clarification.' answered with 'THIS IS WHAT THE SUBJECT WAS TAKING THE MEDICATION FOR.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:20:31
User opened query 'Per DM CLR: Please review Indication and please note that this medication is not typically used as treatment for the indicated condition. Please review and update applicable details as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 10:45:27
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'multiple pulmonary emboli'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '5'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'mg (mg)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'once daily (QD)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'Oral (ORAL)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '10 Sep 2020'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered '0'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
User closed query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or provide clarification for continued use of the medication. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:15:01
Query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or provide clarification for continued use of the medication. Thank you. ' answered with 'UNSURE IF MEDICATION IS ONGOING OR NOT, AS SUBJECT WAS EARLY TERMINATED FROM STUDY FOR MULTIPLE PULMONARY EMBOLI.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	19 Jan 2021 22:58:00
User closed query 'Per DM CLR: RQ: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:53:17
User opened query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or provide clarification for continued use of the medication. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:53:16
Query 'Per DM CLR: RQ: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'CON MEDS WILL BE REVIEWED AND UPDATED AS NECCESSARY' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 16:12:01
User opened query 'Per DM CLR: RQ: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 04:34:49
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:33:03

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'MEDICATION IS STILL ONGOING' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:22:44
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:55:15
User entered 'Yes (Y)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered empty.	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:51:01
User entered 'No (N)'	Meagan Miller (b) (4) (b) (4)	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User entered '1'	System	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User entered '1'	System	02 Oct 2020 18:44:24

US3042190
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:56:56
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User entered '804 (804)'	System	02 Oct 2020 18:44:24

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US3042190
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 14:56:56
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:26:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 22:17:53

US3042190
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 14:56:56
Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 05:09:15
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:25:24
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:19:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:26:01
User entered '17 Sep 2020'	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:24

US3042190
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 14:56:56
Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 05:09:15
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:26:01
User closed query 'Per CDM: per End of Study form subject discontinued due to PI decision related to SAE OF MULTIPLE PULMONARY EMBOLI DIAGNOSI. Please consider updating reason for discontinuation to SAE; and record SAE record number. Also consider updating SAE to IP Withdrawal' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:38:42
Query 'Per CDM: per End of Study form subject discontinued due to PI decision related to SAE OF MULTIPLE PULMONARY EMBOLI DIAGNOSI. Please consider updating reason for discontinuation to SAE; and record SAE record number. Also consider updating SAE to IP Withdrawal' answered with 'updated' (Site from DM).	Jamie Thompson (b) (4) (b) (4)	01 Dec 2020 22:46:33
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	01 Dec 2020 22:46:27
User opened query 'Per CDM: per End of Study form subject discontinued due to PI decision related to SAE OF MULTIPLE PULMONARY EMBOLI DIAGNOSI. Please consider updating reason for discontinuation to SAE; and record SAE record number. Also consider updating SAE to IP Withdrawal' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:16:14
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:24

US3042190
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 14:56:56
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)	29 Apr 2021 05:09:15
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:25:28
User closed query 'Per CDM: Per sponsor review, please update specify field to include number sign. (i.e. SAE #1).' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 08:55:03
Query 'Per CDM: Per sponsor review, please update specify field to include number sign. (i.e. SAE #1).' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:01:24
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:01:18
User entered 'SAE #1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:01:18
User opened query 'Per CDM: Per sponsor review, please update specify field to include number sign. (i.e. SAE #1).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:14:04
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:26:01
User closed query 'Per CDM: Please note that the SAE record number needs to be recorded in this field (eg SAE #1, SAE#2). Kindly update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 07:00:38
Query 'Per CDM: Please note that the SAE record number needs to be recorded in this field (eg SAE #1, SAE#2). Kindly update as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:05:55
User entered 'SAE 1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:05:51
User opened query 'Per CDM: Please note that the SAE record number needs to be recorded in this field (eg SAE #1, SAE#2). Kindly update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:45:32
User closed query 'Per CDM: Please clarify if the patient is discontinued only from further dosing or also from the study. If also discontinued from the study, please fill in the applicable form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:02:27

US3042190

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:56:56

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

Audit	User	Time (GMT)
Query 'Per CDM: Please clarify if the patient is discontinued only from further dosing or also from the study. If also discontinued from the study, please fill in the applicable form. Thank you. ' answered with 'SUBJECT IS DISCONTINUED FROM THE STUDY' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:23:23
User opened query 'Per CDM: Please clarify if the patient is discontinued only from further dosing or also from the study. If also discontinued from the study, please fill in the applicable form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:11:24
User entered 'Due to patients SAE of multiple pulmonary emboli diagnosis, the Primary Investigator decided for the safety of the patient to discontinue them from the study.'	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:24

US3042190
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:56:56
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 05:09:15
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:26:14
User entered '17 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:23:47

US3042190
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:56:56
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 05:09:15
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:26:14
User closed query 'Per CDM: per End of Study form subject discontinued due to PI decision related to SAE OF MULTIPLE PULMONARY EMBOLI DIAGNOSI. Please consider updating reason for discontinuation to SAE and make all applicable updates' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:39:23
Query 'Per CDM: per End of Study form subject discontinued due to PI decision related to SAE OF MULTIPLE PULMONARY EMBOLI DIAGNOSI. Please consider updating reason for discontinuation to SAE and make all applicable updates' answered with 'updated' (Site from DM).	Jamie Thompson (b) (4) (b) (4)	01 Dec 2020 22:46:18
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	01 Dec 2020 22:46:10
User opened query 'Per CDM: per End of Study form subject discontinued due to PI decision related to SAE OF MULTIPLE PULMONARY EMBOLI DIAGNOSI. Please consider updating reason for discontinuation to SAE and make all applicable updates' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:54:52
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:23:47

US3042190
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:56:56
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)	29 Apr 2021 05:09:15
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:25:38
User closed query 'Per CDM: Per sponsor review, please update specify field to include number sign. (i.e. SAE #1).' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 08:55:32
Query 'Per CDM: Per sponsor review, please update specify field to include number sign. (i.e. SAE #1).' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:01:34
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:01:30
User entered 'SAE #1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:01:30
User opened query 'Per CDM: Per sponsor review, please update specify field to include number sign. (i.e. SAE #1).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:26:14
User closed query 'Per CDM: Please note that the SAE record number needs to be recorded in this field (eg SAE #1, SAE#2). Kindly update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 07:01:01
Query 'Per CDM: Please note that the SAE record number needs to be recorded in this field (eg SAE #1, SAE#2). Kindly update as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:06:06
User entered 'SAE 1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:06:02
User opened query 'Per CDM: Please note that the SAE record number needs to be recorded in this field (eg SAE #1, SAE#2). Kindly update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:45:38
User entered 'DUE TO PATIENTS SAE OF MULTIPLE PULMONARY EMBOLI DIAGNOSIS, THE PRIMARY INVESTIGATOR DECIDED FOR THE SAFETY OF THE PATIENT TO DISCONTINUE THEM FROM THE STUDY.'	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:23:47

US3042190
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:56:56
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 05:09:15
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:26:14
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:23:47

FDA-CBER-2022-1614-0185636

US3042190
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:56:56
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 05:09:15
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:26:14
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:23:47

FDA-CBER-2022-1614-0185637

US3042190
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:56:56
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 05:09:15
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:26:14
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:23:47

US3042190
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:56:56
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 05:09:15
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:26:14
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Nov 2020 17:23:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'USA-US052-2020-MRNA-1273-P301000003'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:19
Un-reviewed for Safety.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Meagan'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:41
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:23
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Dec 2020 21:44:53
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Meagan'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	02 Dec 2020 17:21:38
Un-reviewed for Safety.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:32:38
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Meagan'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Meagan'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:20
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Miller'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:44
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:38
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:57
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Miller'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:44
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:33:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Miller'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '330 dakota dunes suite400'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'North sioux'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'IA'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '57049'	System	14 Sep 2020 21:52:07

FDA-CBER-2022-1614-0185655

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:12:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
User entered 'US' (non-conformant).	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '10'	System	18 Dec 2020 13:49:47
User entered '9'	System	11 Dec 2020 17:38:28
User entered '8'	System	03 Nov 2020 16:12:19
User entered '7'	System	21 Oct 2020 14:41:45
User entered '6'	System	19 Oct 2020 20:10:58
User entered '5'	System	06 Oct 2020 16:23:10
User entered '4'	System	05 Oct 2020 12:26:57
User entered '3'	System	18 Sep 2020 15:52:21
User entered '2'	System	16 Sep 2020 19:26:49
User entered '1'	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'USA-US052-2020-MRNA-1273-P301000003'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:19
Un-reviewed for Safety.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Meagan'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:41
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:23
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Dec 2020 21:44:53
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Meagan'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	02 Dec 2020 17:21:38
Un-reviewed for Safety.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:32:38
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Meagan'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Meagan'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:20
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Miller'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:44
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:38
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:57
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Miller'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:44
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:33:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Miller'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '330 dakota dunes suite400'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'North sioux'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'IA'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '57049'	System	14 Sep 2020 21:52:07

FDA-CBER-2022-1614-0185673

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:12:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
User entered 'US' (non-conformant).	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '10'	System	18 Dec 2020 13:49:47
User entered '9'	System	11 Dec 2020 17:38:28
User entered '8'	System	03 Nov 2020 16:12:19
User entered '7'	System	21 Oct 2020 14:41:45
User entered '6'	System	19 Oct 2020 20:10:58
User entered '5'	System	06 Oct 2020 16:23:10
User entered '4'	System	05 Oct 2020 12:26:57
User entered '3'	System	18 Sep 2020 15:52:21
User entered '2'	System	16 Sep 2020 19:26:49
User entered '1'	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 14:56:56
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User entered '11/Sep/2020 11:49'	System	11 Sep 2020 15:49:47

US3042190

Folder: SAE USA-US052-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:56:56

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) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'USA-US052-2020-MRNA-1273-P301000003'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:19
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Meagan'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:41
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:23
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:53
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Meagan'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:38
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:32:38
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Meagan'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Meagan'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:20
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Miller'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:44
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:38
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:57
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Miller'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:44
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:33:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Miller'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '330 dakota dunes suite400'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'North sioux'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'IA'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '57049'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:12:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
User entered 'US' (non-conformant).	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '10'	System	18 Dec 2020 13:49:47
User entered '9'	System	11 Dec 2020 17:38:28
User entered '8'	System	03 Nov 2020 16:12:19
User entered '7'	System	21 Oct 2020 14:41:45
User entered '6'	System	19 Oct 2020 20:10:58
User entered '5'	System	06 Oct 2020 16:23:10
User entered '4'	System	05 Oct 2020 12:26:57
User entered '3'	System	18 Sep 2020 15:52:21
User entered '2'	System	16 Sep 2020 19:26:49
User entered '1'	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 14:56:56
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User entered '16/Sep/2020 15:26'	System	16 Sep 2020 19:26:49

US3042190

Folder: SAE USA-US052-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:56:56

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) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
User entered '1'	(b) (4), (b) (6)	16 Sep 2020 19:26:49

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'USA-US052-2020-MRNA-1273-P301000003'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:19
Un-reviewed for Safety.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Meagan'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:41
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:23
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Dec 2020 21:44:53
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Meagan'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	02 Dec 2020 17:21:38
Un-reviewed for Safety.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:32:38
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Meagan'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Meagan'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:20
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Miller'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:44
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:38
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:57
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Miller'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:44
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:33:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Miller'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '330 dakota dunes suite400'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'North sioux'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'IA'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '57049'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:12:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
User entered 'US' (non-conformant).	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '10'	System	18 Dec 2020 13:49:47
User entered '9'	System	11 Dec 2020 17:38:28
User entered '8'	System	03 Nov 2020 16:12:19
User entered '7'	System	21 Oct 2020 14:41:45
User entered '6'	System	19 Oct 2020 20:10:58
User entered '5'	System	06 Oct 2020 16:23:10
User entered '4'	System	05 Oct 2020 12:26:57
User entered '3'	System	18 Sep 2020 15:52:21
User entered '2'	System	16 Sep 2020 19:26:49
User entered '1'	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 14:56:56
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User entered '18/Sep/2020 11:52'	System	18 Sep 2020 15:52:21

US3042190

Folder: SAE USA-US052-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:56:56

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) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
User entered '1'	(b) (4), (b) (6)	18 Sep 2020 15:52:21

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'USA-US052-2020-MRNA-1273-P301000003'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:19
Un-reviewed for Safety.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Meagan'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:41
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:23
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Dec 2020 21:44:53
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Meagan'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	02 Dec 2020 17:21:38
Un-reviewed for Safety.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:32:38
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Meagan'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Meagan'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:20
Un-reviewed for Safety.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Miller'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:44
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:38
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Dec 2020 21:44:57
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Miller'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	02 Dec 2020 17:21:44
Un-reviewed for Safety.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:33:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Miller'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '330 dakota dunes suite400'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'North sioux'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'IA'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '57049'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:12:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
User entered 'US' (non-conformant).	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '10'	System	18 Dec 2020 13:49:47
User entered '9'	System	11 Dec 2020 17:38:28
User entered '8'	System	03 Nov 2020 16:12:19
User entered '7'	System	21 Oct 2020 14:41:45
User entered '6'	System	19 Oct 2020 20:10:58
User entered '5'	System	06 Oct 2020 16:23:10
User entered '4'	System	05 Oct 2020 12:26:57
User entered '3'	System	18 Sep 2020 15:52:21
User entered '2'	System	16 Sep 2020 19:26:49
User entered '1'	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 14:56:56
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User entered '05/Oct/2020 08:26'	System	05 Oct 2020 12:26:57

US3042190

Folder: SAE USA-US052-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:56:56

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) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 16:23:00
User entered '1'	(b) (4), (b) (6)	05 Oct 2020 12:26:57

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'USA-US052-2020-MRNA-1273-P301000003'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:19
Un-reviewed for Safety.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Meagan'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:41
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:23
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Dec 2020 21:44:53
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Meagan'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	02 Dec 2020 17:21:38
Un-reviewed for Safety.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:32:38
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Meagan'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Meagan'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:20
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Miller'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:44
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:38
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:57
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Miller'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:44
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:33:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Miller'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '330 dakota dunes suite400'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'North sioux'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'IA'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '57049'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:12:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
User entered 'US' (non-conformant).	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '10'	System	18 Dec 2020 13:49:47
User entered '9'	System	11 Dec 2020 17:38:28
User entered '8'	System	03 Nov 2020 16:12:19
User entered '7'	System	21 Oct 2020 14:41:45
User entered '6'	System	19 Oct 2020 20:10:58
User entered '5'	System	06 Oct 2020 16:23:10
User entered '4'	System	05 Oct 2020 12:26:57
User entered '3'	System	18 Sep 2020 15:52:21
User entered '2'	System	16 Sep 2020 19:26:49
User entered '1'	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 14:56:56
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User entered '06/Oct/2020 16:23'	System	06 Oct 2020 16:23:10

FDA-CBER-2022-1614-0185756

US3042190

Folder: SAE USA-US052-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:56:56

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) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 14:40:52
User entered '1'	(b) (4), (b) (6)	06 Oct 2020 16:23:10

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'USA-US052-2020-MRNA-1273-P301000003'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:19
Un-reviewed for Safety.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Meagan'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:41
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:23
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Dec 2020 21:44:53
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Meagan'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	02 Dec 2020 17:21:38
Un-reviewed for Safety.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:32:38
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Meagan'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Meagan'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:20
Un-reviewed for Safety.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Miller'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:44
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:38
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Dec 2020 21:44:57
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Miller'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	02 Dec 2020 17:21:44
Un-reviewed for Safety.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:33:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Miller'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '330 dakota dunes suite400'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'North sioux'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'IA'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '57049'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:12:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
User entered 'US' (non-conformant).	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '10'	System	18 Dec 2020 13:49:47
User entered '9'	System	11 Dec 2020 17:38:28
User entered '8'	System	03 Nov 2020 16:12:19
User entered '7'	System	21 Oct 2020 14:41:45
User entered '6'	System	19 Oct 2020 20:10:58
User entered '5'	System	06 Oct 2020 16:23:10
User entered '4'	System	05 Oct 2020 12:26:57
User entered '3'	System	18 Sep 2020 15:52:21
User entered '2'	System	16 Sep 2020 19:26:49
User entered '1'	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (6)
Generated On: 09 Jun 2021 14:56:56
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User entered '19/Oct/2020 16:10'	System	19 Oct 2020 20:10:58

US3042190

Folder: SAE USA-US052-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:56:56

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) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 14:40:52
User entered '1'	(b) (4), (b) (6)	19 Oct 2020 20:10:58

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'USA-US052-2020-MRNA-1273-P301000003'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:19
Un-reviewed for Safety.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Meagan'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:41
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:23
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Dec 2020 21:44:53
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Meagan'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	02 Dec 2020 17:21:38
Un-reviewed for Safety.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:32:38
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Meagan'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Meagan'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:20
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Miller'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:44
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:38
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:57
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Miller'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:44
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34

FDA-CBER-2022-1614-0185788

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:33:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Miller'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '330 dakota dunes suite400'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'North sioux'	System	14 Sep 2020 21:52:07

FDA-CBER-2022-1614-0185791

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'IA'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '57049'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:12:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
User entered 'US' (non-conformant).	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '10'	System	18 Dec 2020 13:49:47
User entered '9'	System	11 Dec 2020 17:38:28
User entered '8'	System	03 Nov 2020 16:12:19
User entered '7'	System	21 Oct 2020 14:41:45
User entered '6'	System	19 Oct 2020 20:10:58
User entered '5'	System	06 Oct 2020 16:23:10
User entered '4'	System	05 Oct 2020 12:26:57
User entered '3'	System	18 Sep 2020 15:52:21
User entered '2'	System	16 Sep 2020 19:26:49
User entered '1'	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (7)
Generated On: 09 Jun 2021 14:56:56
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User entered '21/Oct/2020 14:41'	System	21 Oct 2020 14:41:45

US3042190

Folder: SAE USA-US052-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:56:56

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) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 14:42:36
User entered '1'	(b) (4), (b) (6)	21 Oct 2020 14:41:45

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'USA-US052-2020-MRNA-1273-P301000003'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:19
Un-reviewed for Safety.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Meagan'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:41
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:23
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Dec 2020 21:44:53
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Meagan'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	02 Dec 2020 17:21:38
Un-reviewed for Safety.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34

FDA-CBER-2022-1614-0185806

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:32:38
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Meagan'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Meagan'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:20
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Miller'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:44
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:38
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:57
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Miller'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:44
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34

FDA-CBER-2022-1614-0185808

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:33:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Miller'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '330 dakota dunes suite400'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'North sioux'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'IA'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '57049'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:12:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
User entered 'US' (non-conformant).	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '10'	System	18 Dec 2020 13:49:47
User entered '9'	System	11 Dec 2020 17:38:28
User entered '8'	System	03 Nov 2020 16:12:19
User entered '7'	System	21 Oct 2020 14:41:45
User entered '6'	System	19 Oct 2020 20:10:58
User entered '5'	System	06 Oct 2020 16:23:10
User entered '4'	System	05 Oct 2020 12:26:57
User entered '3'	System	18 Sep 2020 15:52:21
User entered '2'	System	16 Sep 2020 19:26:49
User entered '1'	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (8)
Generated On: 09 Jun 2021 14:56:56
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User entered '03/Nov/2020 16:12'	System	03 Nov 2020 16:12:19

US3042190

Folder: SAE USA-US052-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:56:56

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) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 16:12:19

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'USA-US052-2020-MRNA-1273-P301000003'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:19
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Meagan'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:41
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:23
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:53
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Meagan'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:38
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:32:38
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Meagan'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Meagan'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:20
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Miller'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:44
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:38
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:57
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Miller'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:44
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34

FDA-CBER-2022-1614-0185828

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:33:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Miller'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '330 dakota dunes suite400'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'North sioux'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'IA'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '57049'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:12:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
User entered 'US' (non-conformant).	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '10'	System	18 Dec 2020 13:49:47
User entered '9'	System	11 Dec 2020 17:38:28
User entered '8'	System	03 Nov 2020 16:12:19
User entered '7'	System	21 Oct 2020 14:41:45
User entered '6'	System	19 Oct 2020 20:10:58
User entered '5'	System	06 Oct 2020 16:23:10
User entered '4'	System	05 Oct 2020 12:26:57
User entered '3'	System	18 Sep 2020 15:52:21
User entered '2'	System	16 Sep 2020 19:26:49
User entered '1'	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (9)
Generated On: 09 Jun 2021 14:56:56
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
User entered '11/Dec/2020 09:38'	System	11 Dec 2020 17:38:28

US3042190

Folder: SAE USA-US052-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 14:56:56

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) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
User entered '1'	(b) (4), (b) (6)	11 Dec 2020 17:38:28

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'USA-US052-2020-MRNA-1273-P301000003'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'Yes (Y)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 15:49:41
User entered 'No (N)'	System	11 Sep 2020 15:42:00

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:19
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Meagan'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:41
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:23
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:53
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:38:58
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Meagan'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:38
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's First Name

Audit	User	Time (GMT)
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:32:38
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Meagan'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'David' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Meagan'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:35:20
Un-reviewed for Safety.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Un-verified.	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4)	29 Jan 2021 19:23:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
Un-reviewed for Safety.	System	18 Dec 2020 13:49:47
DataPoint Un-verified.	System	18 Dec 2020 13:49:47
User entered 'Miller'	System	18 Dec 2020 13:49:47
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:48:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:44
User closed query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:35:38
Query 'Should be PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Dec 2020 21:44:57
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 21:44:47
User opened query 'Should be PI's name' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:39:21
Un-reviewed for Safety.	System	11 Dec 2020 17:38:28
User entered 'Miller'	System	11 Dec 2020 17:38:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:38:14
Query 'Should be PI's name, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	02 Dec 2020 17:21:44
Un-reviewed for Safety.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34
DataPoint Un-verified.	Rylea Gulick (b) (4)	02 Dec 2020 17:21:34

FDA-CBER-2022-1614-0185848

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator's Last Name

Audit	User	Time (GMT)
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:33:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:26:46
Un-reviewed for Safety.	System	18 Sep 2020 15:52:21
User entered 'Miller'	System	18 Sep 2020 15:52:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:52:07
Un-reviewed for Safety.	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
User entered 'Ensz' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Sep 2020 00:01:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '330 dakota dunes suite400'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'North sioux'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered 'IA'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
Amendment Manager: User entered '57049'	System	14 Sep 2020 21:52:07

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:34:24
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:12:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 19:26:37
User entered 'US' (non-conformant).	System	11 Sep 2020 15:49:47

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:56:56
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User entered '10'	System	18 Dec 2020 13:49:47
User entered '9'	System	11 Dec 2020 17:38:28
User entered '8'	System	03 Nov 2020 16:12:19
User entered '7'	System	21 Oct 2020 14:41:45
User entered '6'	System	19 Oct 2020 20:10:58
User entered '5'	System	06 Oct 2020 16:23:10
User entered '4'	System	05 Oct 2020 12:26:57
User entered '3'	System	18 Sep 2020 15:52:21
User entered '2'	System	16 Sep 2020 19:26:49
User entered '1'	System	11 Sep 2020 15:49:47

FDA-CBER-2022-1614-0185855

US3042190
Folder: SAE USA-US052-2020-MRNA-1273-P301000003
Form: Safety Report Form (10)
Generated On: 09 Jun 2021 14:56:56
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
User entered '18/Dec/2020 05:49'	System	18 Dec 2020 13:49:47

US3042190

Folder: SAE USA-US052-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 14:56:56

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) (b) (4), (b) (6)	02 May 2021 13:11:18
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 09:57:58
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:27:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 13:50:06
User entered '1'	(b) (4), (b) (6)	18 Dec 2020 13:49:47