US3342256 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:06:55

All time stamps listed in this document are displayed in GMT

Participant ID   US3342256

mRNA-1273-P301 Completion Guidelines

US3342256

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **12 Mar 2021 23:18:27**

Generated On: 09 Jun 2021 17:06:55

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Date of Birth (MMM yyyy)	(b) (6) 1977
Age	43
Age Units	YEARS
Age (Derived)	43
Sex	Female ◯
	Male ⬤
Ethnicity	Hispanic or Latino ◯
	Not Hispanic or Latino ⬤
	Not Reported ◯
	Unknown ◯

Race (Check All That Apply)	
White	False
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	True
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) **12 Mar 2021 23:18:26**

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Date of Informed Consent *(dd MMM yyyy)*	14 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **12 Mar 2021 23:18:26**

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Did the participant meet all eligibility criteria?   Yes ●

                                                            No ○

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) **12 Mar 2021 23:18:27**

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Were any significant conditions reported?   Yes ●

                                              No ○

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Condition	DIVERTICULOSIS
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Condition	GASTRIC SLEEVE SURGERY
Start date (dd MMM yyyy)	UN MAY 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2014
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2014
Start Year (derived)	2014
Stop Month and Year (derived)	MAY 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Condition	TOOTH EXTRACTION
Start date (dd MMM yyyy)	UN JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Condition	TOOTH INFECTION
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 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3342256

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3342256

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

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

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Folder: Screening

Form: Medical History (10)

Data signed: ▓(b) (4)▓ **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Condition	LEFT VENTRICULAR HYPERTROPHY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **12 Mar 2021 23:18:27**

Generated On: 09 Jun 2021 17:06:55

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	14 SEP 2020
Time of assessment *(00:00-23:59)*	08:37 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 08:37
Height *(xxx.x)*	188.5 cm
Weight *(xxx.x)*	102.9 kg
BMI *(xxx.x)*	28.95961 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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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **12 Mar 2021 23:18:27**

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Was the physical examination performed?   Yes ●

                                                                                                          No ◯

Date of examination *(dd MMM yyyy)*   14 SEP 2020

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

US3342256
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **12 Mar 2021 23:18:27**
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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes	○
	No	●
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes	○
	No	●
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes	○
	No	●
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes	○
	No	●
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes	○
	No	●
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes	●
	No	○
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes	○
	No	●
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes	○
	No	●
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes	○
	No	●
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes	○
	No	●
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes	○
	No	●
Other	Yes	○
	No	●

   Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **12 Mar 2021 23:18:27**

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **12 Mar 2021 23:18:27**

Generated On: 09 Jun 2021 17:06:55

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **12 Mar 2021 23:18:27**

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What was the date of randomization? *(dd MMM yyyy)*	14 SEP 2020
What was the participant's randomization number?	113647

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

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

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **12 Mar 2021 23:18:27**

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **12 Mar 2021 23:18:27**

Generated On: 09 Jun 2021 17:06:55

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)*	14 SEP 2020
Time of assessment *(00:00-23:59)*	08:37 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 08:37
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **12 Mar 2021 23:18:27**

Generated On: 09 Jun 2021 17:06:55

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)*	14 SEP 2020
Time of assessment *(00:00-23:59)*	10:23 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 10:23
Temperature *(xxx.x)*	96.7 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **12 Mar 2021 23:18:27**

Generated On: 09 Jun 2021 17:06:55

Was the physical examination performed?   Yes ◯

                                                                          No ⬤

Date of examination *(dd MMM yyyy)*   _____

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

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)*	14 SEP 2020
What was the treatment time? *(00:00-23:59)*	09:51 (24 HR)
Treatment Date and Time (derived)	14 SEP 2020 09:51
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **12 Mar 2021 23:18:27**

Generated On: 09 Jun 2021 17:06:55

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	14 SEP 2020
Collection time *(00:00-23:59)*	09:21 (24 HR)
Collection date and time (derived)	14 SEP 2020 09:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **12 Mar 2021 23:18:27**

Generated On: 09 Jun 2021 17:06:55

Collection date *(dd MMM yyyy)*			14 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:25	14 SEP 2020 09:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **12 Mar 2021 23:18:27**

Generated On: 09 Jun 2021 17:06:55

Is the participant continuing to the next visit?　　　　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　1

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**	96.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	14 SEP 2020 10:25
PC Open Date & Time	14 SEP 2020 10:11
PC Close Date & Time	14 SEP 2020 12:41

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**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	14 SEP 2020 20:25
PC Open Date & Time	14 SEP 2020 13:36
PC Close Date & Time	15 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:55

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**	97.8 °F

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

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

PC Time Stamp	15 SEP 2020 21:49
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

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Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:06:55

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	16 SEP 2020 21:10
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:55

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.3 °F

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

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 SEP 2020 03:49
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:06:55

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.5 °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	18 SEP 2020 20:04
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:55

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**	97.6 °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	20 SEP 2020 00:22
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

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	14 SEP 2020 10:26
PC Open Date & Time	14 SEP 2020 10:11
PC Close Date & Time	14 SEP 2020 12:41

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

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 SEP 2020 20:26
PC Open Date & Time	14 SEP 2020 13:36
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-2823947

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:55

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	15 SEP 2020 21:49
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:55

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	16 SEP 2020 21:10
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:55

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	18 SEP 2020 03:49
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

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 SEP 2020 20:04
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

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	20 SEP 2020 00:22
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:06:55

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 ◯

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯

PC Time stamp	14 SEP 2020 10:26
PC Open Date & Time	14 SEP 2020 10:11
PC Close Date & Time	14 SEP 2020 12:41

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:06:55

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 ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No	●
	Yes	○

PC Time stamp	14 SEP 2020 20:26
PC Open Date & Time	14 SEP 2020 13:36
PC Close Date & Time	15 SEP 2020 11:59

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 ⬤

	Yes ◯
PC Time stamp	15 SEP 2020 21:50
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:55

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 ●

	Yes ◯
PC Time stamp	16 SEP 2020 21:11
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:55

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-2022-1614-2823961

	Yes ◯
PC Time stamp	18 SEP 2020 03:49
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:06:55

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 ●

	Yes ◯
PC Time stamp	18 SEP 2020 20:05
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:06:55

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 ●

	Yes ◯
PC Time stamp	20 SEP 2020 00:22
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3342256

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **29 Mar 2021 15:32:02**

Generated On: 09 Jun 2021 17:06:55

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 SEP 2020
Please select one status for the follow-up contact	Contact Made ○
	Contact Not Made ●
Comments	LEFT A VOICEMAIL ONCE EACH DAY FROM 21SEP2020 TO 24SEP2020. ALSO SENT AN EMAIL ON 23SEP2020.
If Contact Not Made, please provide Comments	

US3342256
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 23:18:26**
Generated On: 09 Jun 2021 17:06:55

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3342256

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	01 OCT 2020
Please select one status for the follow-up contact	Contact Made ○
	Contact Not Made ●
Comments	LEFT A VOICEMAIL ONCE EACH DAY FROM 29SEP2020 -
If Contact Not Made, please provide Comments	01OCT2020. ALSO SENT A TEXT REMINDER ON 01OCT2020.

US3342256

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Is the participant continuing to the next visit?   Yes ●

                                                                          No ○

Continuing Flag   1

US3342256

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **29 Mar 2021 15:32:02**

Generated On: 09 Jun 2021 17:06:55

| Was Contact Attempted? | Yes ● |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 08 OCT 2020 |

| Please select one status for the follow-up contact | Contact Made ◯ |
| | Contact Not Made ● |

| Comments | SEE SAE NARRATIVE REGARDING DEATH |

If Contact Not Made, please provide Comments

US3342256
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 23:18:26**
Generated On: 09 Jun 2021 17:06:55

Is the participant continuing to the next visit?   Yes ◯

                                                                                        No ⬤

Continuing Flag

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:06:55

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

US3342256
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:06:55

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 ◯

Generate Next COVID-19 Assessment	Yes ◯
	No ◯

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 _____

US3342256

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:55

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)	

US3342256

Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 17:06:55

Was the sample collected?	Yes	◯
	No	◯

Collection date *(dd MMM yyyy)*	
Collection time *(00:00 - 23:59)*	
Collection Date and Time (derived)	

FDA-CBER-2022-1614-2823979

US3342256

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Did the participant experience any adverse events?   Yes ⬤

No ◯

If Yes, enter details on the Adverse Events form.

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

AEID	USA-US203-2020-MRNA-1273-P30 1000003
Adverse event	CARDIOPULMONARY ARREST
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)*	20 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)*	20 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	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○ No ○ Unknown ○

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

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	True

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

SUBJECT'S SPOUSE CALLED SITE 08OCT2020 TO INFORM OF PASSING OF SUBJECT ON 20SEP2020 DUE TO MI; SPOUSE STATES THAT PATIENT HAD HISTORY OF HEART DISEASE. SITE PENDING MEDICAL RECORDS AND AUTOPSY REPORT. CONMED ADMINISTRATION UNKNOWN AT TIME OF INITIAL REPORT.

SITE RECEIVED MEDICAL EXAMINER RECORDS 26JAN2021. CAUSE OF DEATH STATEMENT STATES ARTHEROSCLEROTIC AND HYPERTENSIVE CARDIOVASCULAR DISEASE, MANNER OF DEATH NATURAL. REPORT STATES 43-Y/O MAN WAS WITNESSED COLLAPSE IN ER WHERE HE PRESENTED BY PRIVATE VEHICLE W/ CHEST PAIN AND SOB. RESUSCITATION UNSUCCESSFUL. AUTOPSY SHOWED CARDIOMEGALY, LV HYPERTROPHY, ARTHEROSCLEROSIS AND STENOSIS OF CORONARY ARTERIES, WITH ARTERIOLENEPHROSCLEROSIS WHICH IS COMMONLY SEEN IN THOSE WITH HIGH BP.

POSTMORTEM TOXICOLOGY
SHOWED PRESENCE OF ETOH
0.05% FEMORAL BLOOD AND
0.06% VITREOUS.

EVIDENCE OF MEDICAL
INTERVENTION INCLUDE
ENDOTRACHEAL TUBE,
DEFIBRILLATOR PADS AFFIXED
TO TORSO, ECG AFFIXED TO
TORSO AND UPPER
EXTREMITIES,
INTRAVASCULAR CATHETER
FROM R ANTECUBITAL FOSSA,;
INJURIES RELATED TO
RESUSCITATIVE ATTEMPTS
SHOW BL ANTEROLATERAL
RIB FRACTURES WITH ASSOC.
INTERCOSTAL MUSCLE
HEMORRHAGE AND
PANCREATIC HEMORRHAGE.
POSTMORTEM CT
ADDITIONALLY REVEALED
CARDIOMEGALY AND FOCAL
CORONARY ARTERY
CALCIFICATION

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)	

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

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

                                                                           No ◯

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Name of Medication	ADVIL
Prophylaxis	Yes ◯
	No ⬤
Indication	HEADACHES
Dose per administration	400
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)*	UN UNK 2008
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 ◯

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **22 Mar 2021 13:27:39**

Generated On: 09 Jun 2021 17:06:55

Were any concomitant procedures performed?   Yes ⬤

                                                                              No ◯

If yes, please complete Concomitant Procedures form.

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **29 Mar 2021 22:08:51**

Generated On: 09 Jun 2021 17:06:55

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
20 SEP 2020	ENDOTRACHEAL INTUBATION	Adverse Event	
20 SEP 2020	DEFIBRILLATION	Adverse Event	
20 SEP 2020	ELECTROCARDIOGRAM	Adverse Event	
20 SEP 2020	INTRAVASCULAR CATHETERIZATION RIGHT ANTECUBITAL FOSSA	Adverse Event	
21 SEP 2020	POSTMORTEM CT SCAN	Adverse Event	
02 OCT 2020	TOXICOLOGY LABS POSTMORTEM	Adverse Event	

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

Date of dosing discontinuation (dd MMM yyyy)	20 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

_____

FDA-CBER-2022-1614-2823990

Date of study discontinuation/completion *(dd MMM yyyy)*	20 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	
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)*	20 SEP 2020
Was autopsy performed?	Yes ●
	No ◯
	Unknown ◯

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

SAEID	USA-US203-2020-MRNA-1273-P30 1000003
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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

SAEID	USA-US203-2020-MRNA-1273-P30 1000003
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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/OCT/2020 15:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

SAEID	USA-US203-2020-MRNA-1273-P30 1000003
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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/OCT/2020 09:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

SAEID	USA-US203-2020-MRNA-1273-P30 1000003
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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/JAN/2021 15:23
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

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) **12 Mar 2021 23:18:26**

Generated On: 09 Jun 2021 17:06:55

SAEID	USA-US203-2020-MRNA-1273-P30 1000003
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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/FEB/2021 10:41
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

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Data signed: (b) (4) **12 Mar 2021 23:18:26**
Generated On: 09 Jun 2021 17:06:55

SAEID	USA-US203-2020-MRNA-1273-P30 1000003
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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/FEB/2021 11:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3342256 (Prod: Tekton Research- Austin)

US3342256

Form: Participant Creation

Generated On: 09 Jun 2021 17:06:55

Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:15:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
User entered 'US3342256'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Sep 2020 13:45:18

US3342256
Form: Participant Creation
Generated On: 09 Jun 2021 17:06:55

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14

US3342256

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:55

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:07:01
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:40:23

US3342256

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:07:01
User entered '14 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Sep 2020 13:45:20

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US3342256
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:01
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4)	14 Sep 2020 14:40:23

US3342256
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:06:55
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'SCRN'	System	14 Sep 2020 14:40:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
User entered (b) (6) 1977'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Sep 2020 13:45:22

FDA-CBER-2022-1614-2824005

US3342256

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:55

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '43'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:55

Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'YEARS'	System	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:55

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '43'	System	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:55

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Male (M)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:55

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Morgan Schulle (b) (4)	14 Sep 2020 14:41:05
	(b) (4)	

US3342256

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:55

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:06:55
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:55

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:06:55

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:55

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:06:55
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:55

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '1'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:55

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:20

FDA-CBER-2022-1614-2824020

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'Sep 2020'	System	14 Sep 2020 14:41:20

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '2020'	System	14 Sep 2020 14:41:20

FDA-CBER-2022-1614-2824022

US3342256

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:55

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Amendment 3 (3)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:55

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:55

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:20

FDA-CBER-2022-1614-2824026

US3342256

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:55

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:55

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Sep 2020 13:45:20

US3342256
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:06:55
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '1'	System	14 Sep 2020 14:41:25

US3342256

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:06:55

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:25

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:06:55

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:38

FDA-CBER-2022-1614-2824031

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum, LLT: Diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:43:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:43:46
Data point term sent to Coder	System	14 Sep 2020 14:43:09
User entered 'DIVERTICULOSIS'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'UN UNK 2010'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:55

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:20

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:55

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'Jan 2010'	System	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '2010'	System	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:55

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:55

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	14 Sep 2020 14:42:20

US3342256
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:06:55
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:43:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:43:46
Data point term sent to Coder	System	14 Sep 2020 14:43:09
User entered 'GASTRIC SLEEVE SURGERY'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'UN May 2014'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:49

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'UN May 2014'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:49

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:49

FDA-CBER-2022-1614-2824047

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'May 2014'	System	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '2014'	System	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:55

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'May 2014'	System	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:55

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '2014'	System	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:43:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:43:47
Data point term sent to Coder	System	14 Sep 2020 14:43:09
User entered 'HEADACHES'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'UN UNK 2007'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:55

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 14:43:05
	(b) (4)	

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:05

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:55

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'Jan 2007'	System	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '2007'	System	14 Sep 2020 14:43:05

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:55

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	14 Sep 2020 14:43:05

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	14 Sep 2020 14:43:05

FDA-CBER-2022-1614-2824061

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Tooth extraction, LLT: Tooth extraction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:44:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:44:51
Data point term sent to Coder	System	14 Sep 2020 14:44:10
User entered 'TOOTH EXTRACTION'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'UN Jul 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:55

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'UN Jul 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:30

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:55

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:30

FDA-CBER-2022-1614-2824067

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'Jul 2020'	System	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '2020'	System	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:55

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'Jul 2020'	System	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:55

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '2020'	System	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth infection, LLT: Tooth infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:44:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:44:49
Data point term sent to Coder	System	14 Sep 2020 14:44:10
User entered 'TOOTH INFECTION'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'UN Jun 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:55

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:53

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'UN Jul 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:55

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'Jun 2020'	System	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '2020'	System	14 Sep 2020 14:43:53

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:55

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'Jul 2020'	System	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:55

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '2020'	System	14 Sep 2020 14:43:53

US3342256
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:06:55
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 22:44:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 22:44:23
Data point term sent to Coder	System	28 Jan 2021 22:43:48
User entered 'obesity'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:15

US3342256

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:15

US3342256
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:06:55
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '1'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:15

US3342256

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:55

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:15

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:55

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:15

US3342256

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:15

US3342256
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:06:55
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:15

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:15

FDA-CBER-2022-1614-2824090

US3342256
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:06:55
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:15

US3342256

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Cardiomegaly, LLT: Cardiomegaly - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 22:44:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 22:44:23
Data point term sent to Coder	System	28 Jan 2021 22:43:48
User entered 'cardiomegaly'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:26

US3342256

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:26

US3342256

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '1'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:26

US3342256

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:55

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:26

US3342256

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Eileen Euperio (b) (4)	28 Jan 2021 22:43:26

US3342256

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:55

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:26

US3342256

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:26

US3342256

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:26

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:26

FDA-CBER-2022-1614-2824100

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:26

US3342256

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 22:44:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 22:44:24
Data point term sent to Coder	System	28 Jan 2021 22:43:48
User entered 'coronary artery disease'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '1'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:38

US3342256

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:55

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:38

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:38

US3342256

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:55

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:38

US3342256

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:38

US3342256

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:38

US3342256

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:55

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:38

US3342256

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:55

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:38

US3342256

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User coded data point as SOC: Renal and urinary disorders, HLGT: Nephropathies, HLT: Nephropathies and tubular disorders NEC, PT: Nephrosclerosis, LLT: Nephrosclerosis arteriolar - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jan 2021 20:31:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jan 2021 20:31:30
Data point term sent to Coder	System	28 Jan 2021 22:44:48
User entered 'arterionephrosclerosis'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:59

US3342256

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:59

US3342256

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '1'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:59

US3342256

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:55

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:59

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:59

US3342256

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:55

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:43:59

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:59

Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:06:55
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:59

US3342256

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:55

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:59

US3342256

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:55

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	28 Jan 2021 22:43:59

US3342256

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Left ventricular hypertrophy, LLT: Left ventricular hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 20:52:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 20:52:00
Data point term sent to Coder	System	25 Feb 2021 20:51:00
User entered 'left ventricular hypertrophy'	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:50:27

FDA-CBER-2022-1614-2824123

US3342256

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '1'	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:50:27

US3342256

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:55

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:50:27

FDA-CBER-2022-1614-2824126

US3342256

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:55

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:50:27

Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	25 Feb 2021 20:50:27

US3342256
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:06:55
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	25 Feb 2021 20:50:27

US3342256

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:55

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	25 Feb 2021 20:50:27

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	25 Feb 2021 20:50:27

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:06:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:55

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '08:37'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '14 Sep 2020 08:37'	System	14 Sep 2020 14:45:12

US3342256
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:06:55

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '188.5' cm	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12
DataPoint set to visible.	System	14 Sep 2020 14:41:25

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:55

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '102.9' kg	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12
DataPoint set to visible.	System	14 Sep 2020 14:41:25

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:55

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '28.95961'	System	14 Sep 2020 14:45:12
DataPoint set to visible.	System	14 Sep 2020 14:41:25

US3342256
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:06:55
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'kg/m2'	System	14 Sep 2020 14:45:12
DataPoint set to visible.	System	14 Sep 2020 14:41:25

US3342256
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:06:55
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

US3342256
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:06:55
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

FDA-CBER-2022-1614-2824142

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:06:55

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

US3342256
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:06:55
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'bpm'	System	14 Sep 2020 14:45:12

US3342256
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:06:55

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'breaths/min'	System	14 Sep 2020 14:45:12

FDA-CBER-2022-1614-2824146

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:55

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

US3342256
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:06:55
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'mmHg'	System	14 Sep 2020 14:45:12

US3342256
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:06:55
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered 'mmHg'	System	14 Sep 2020 14:45:12

US3342256
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:06:55
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45

US3342256
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:06:55
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45

US3342256
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:06:55

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:21

US3342256

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:55

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:21

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:06:55
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 14:46:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 14:46:03
User entered 'No (N)' reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:46:03
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 14:45:52
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:06:55
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:06:55
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '1'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:55

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:55

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:46:19

US3342256

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:46:19

US3342256

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:46:19

US3342256
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:06:55
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered 'VISIT1'	System	14 Sep 2020 14:46:19

US3342256

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:14:39
User entered '14 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Sep 2020 14:15:14

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:55

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:14:39
User entered '113647'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Sep 2020 14:15:14

US3342256

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:55

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:14:39
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Sep 2020 14:15:14

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:14:39
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:46:40

US3342256

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:55

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)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:14:39
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:46:40

US3342256

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:14:39
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:46:40

US3342256

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:55

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:14:39
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:46:40

US3342256

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:55

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:14:39
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:46:40

US3342256

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:55

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 16:10:47
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Answered' (Site from DM).	Olivia Hapanowicz (b) (4)	07 Dec 2020 14:20:21
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	07 Dec 2020 14:20:17
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 22:51:28
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:08:29
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:08:28

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered missing code ND - Not Done.	Morgan Schulle (b) (4)	14 Sep 2020 14:47:25
	(b) (4)	

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:06:55

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User accepted default value 'Pre-Dose (PREDOSE)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered '14 Sep 2020'	Morgan Schulle (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered '08:37'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered '14 Sep 2020 08:37'	System	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered '98.3' F	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered 'Oral (Oral)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered '76'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered 'bpm'	System	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered '14'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered 'breaths/min'	System	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered '113'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered 'mmHg'	System	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered '78'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered 'mmHg'	System	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User accepted default value 'Post-Dose (POSTDOSE)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 14:47:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 15:26:10
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 15:26:10
User entered '10:23' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 15:26:10
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 14:47:25
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered '14 Sep 2020 10:23'	System	14 Sep 2020 15:26:10
User entered empty.	System	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:15:00
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 05:49:36
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Darrell O'Brien (b) (4) (b) (4)	02 Oct 2020 18:39:19
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:34:23
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 15:26:10
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 15:26:10
User entered '96.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 15:26:10
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 14:47:25
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 15:26:10
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:15:00
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 15:26:10
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 15:26:10
User entered '60' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 15:26:10
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 14:47:25
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered 'bpm'	System	14 Sep 2020 15:26:10
User entered empty.	System	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 15:26:10
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 15:26:10
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 15:26:10
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 14:47:25
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered 'breaths/min'	System	14 Sep 2020 15:26:10
User entered empty.	System	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:15:00
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 15:26:10
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 15:26:10
User entered '125' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 15:26:10
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 14:47:25
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered 'mmHg'	System	14 Sep 2020 15:26:10
User entered empty.	System	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:15:00
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 15:26:10
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 15:26:10
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 15:26:10
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 14:47:25
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered 'mmHg'	System	14 Sep 2020 15:26:10
User entered empty.	System	14 Sep 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:55

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:10
User entered 'No (N)'	Morgan Schulle (b) (4)	14 Sep 2020 14:47:31

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:55

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:15:10
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:31

US3342256
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:06:55
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:25
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	14 Sep 2020 15:14:42
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	14 Sep 2020 15:14:42
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	14 Sep 2020 14:47:39
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:39

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:06:55
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:25
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:39

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Form: Exposure

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:15:25
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:39

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:06:55
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 14:47:39

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:25
User entered '14 Sep 2020'	Morgan Schulle (b) (4)	14 Sep 2020 14:47:39

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:15:25
User entered '09:51' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 15:14:42
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:39

US3342256
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:06:55

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered '14 Sep 2020 09:51'	System	14 Sep 2020 15:14:42
User entered empty.	System	14 Sep 2020 14:47:39

US3342256

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:55

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:25
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 15:14:42
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 14:47:39

US3342256

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:25
User entered 'ONCE'	System	14 Sep 2020 14:47:39

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:06:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 14:47:39

US3342256

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:55

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:30
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:48:09

US3342256

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:55

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:30
User entered '14 Sep 2020'	Morgan Schulle (b) (4)	14 Sep 2020 14:48:09
	(b) (4)	

US3342256

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:55

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:15:30
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 15:13:34
User entered '09:21' reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 15:13:34
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 14:48:09
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:48:09

US3342256

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered '14 Sep 2020 09:21'	System	14 Sep 2020 15:13:34
User entered empty.	System	14 Sep 2020 14:48:09

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:15:55
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:49:27

FDA-CBER-2022-1614-2824243

US3342256

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:55

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:49:27

US3342256

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:55

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:55
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:49:27

US3342256

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:55

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:55
User closed query ''Was the sample collected?' is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 15:13:42
Query ''Was the sample collected?' is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	14 Sep 2020 15:13:42
User entered '09:25' reason for change: Data Entry Error	Morgan Schulle (b) (4)	14 Sep 2020 15:13:42
User opened query ''Was the sample collected?' is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 14:49:27
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 14:49:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered '14 Sep 2020 09:25'	System	14 Sep 2020 15:13:42
User entered empty.	System	14 Sep 2020 14:49:27

US3342256

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:55

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:49:27

US3342256

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:55

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:15:55
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:49:27

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:55
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 14:49:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered empty.	System	14 Sep 2020 14:49:27

US3342256

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:06:55

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:16:05
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:49:34

US3342256

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:06:55

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:06
User entered '1'	System	14 Sep 2020 14:49:34

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:24:39', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '33b9d372-cd83-446a-8b2b-7a5bf3806ef0'	System	14 Sep 2020 15:25:12
User entered 'Yes (Y)'	System	14 Sep 2020 15:25:12

US3342256
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:06:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:24:45', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '33b9d372-cd83-446a-8b2b-7a5bf3806ef0'	System	14 Sep 2020 15:25:12
User entered '96.7'	System	14 Sep 2020 15:25:12

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:24:53', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '33b9d372-cd83-446a-8b2b-7a5bf3806ef0'	System	14 Sep 2020 15:25:12
User entered 'No (N)'	System	14 Sep 2020 15:25:12

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:25:08', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '33b9d372-cd83-446a-8b2b-7a5bf3806ef0'	System	14 Sep 2020 15:25:12
User entered '14 Sep 2020 10:25'	System	14 Sep 2020 15:25:12

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '14 Sep 2020 10:11'	System	14 Sep 2020 15:14:42

Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:06:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '14 Sep 2020 12:41'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:25:33', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '47c2e8ea-1dc2-405f-b8ba-d4c1b2f5e49a'	System	15 Sep 2020 01:25:50
User entered 'Yes (Y)'	System	15 Sep 2020 01:25:50

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:25:37', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '47c2e8ea-1dc2-405f-b8ba-d4c1b2f5e49a'	System	15 Sep 2020 01:25:50
User entered '97.3'	System	15 Sep 2020 01:25:50

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:25:42', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '47c2e8ea-1dc2-405f-b8ba-d4c1b2f5e49a'	System	15 Sep 2020 01:25:50
User entered 'No (N)'	System	15 Sep 2020 01:25:50

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:25:46', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '47c2e8ea-1dc2-405f-b8ba-d4c1b2f5e49a'	System	15 Sep 2020 01:25:50
User entered '14 Sep 2020 20:25'	System	15 Sep 2020 01:25:50

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '14 Sep 2020 13:36'	System	14 Sep 2020 15:14:42

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US3342256
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:06:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 2'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:49:05', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e93539d6-a6fc-4dd4-8847-1ecf9e92c7fd'	System	16 Sep 2020 02:50:32
User entered 'Yes (Y)'	System	16 Sep 2020 02:50:32

US3342256
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:06:55

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:49:12', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e93539d6-a6fc-4dd4-8847-1ecf9e92c7fd'	System	16 Sep 2020 02:50:32
User entered '97.8'	System	16 Sep 2020 02:50:32

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:49:16', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e93539d6-a6fc-4dd4-8847-1ecf9e92c7fd'	System	16 Sep 2020 02:50:32
User entered 'No (N)'	System	16 Sep 2020 02:50:32

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US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:55

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:49:20', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e93539d6-a6fc-4dd4-8847-1ecf9e92c7fd'	System	16 Sep 2020 02:50:32
User entered '15 Sep 2020 21:49'	System	16 Sep 2020 02:50:32

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

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US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 3'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:29', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'be0babe9-ed48-4c70-80fe-1e594176bd3c'	System	17 Sep 2020 02:10:41
User entered 'Yes (Y)'	System	17 Sep 2020 02:10:41

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:55

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:33', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'be0babe9-ed48-4c70-80fe-1e594176bd3c'	System	17 Sep 2020 02:10:41
User entered '97.5'	System	17 Sep 2020 02:10:41

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:36', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'be0babe9-ed48-4c70-80fe-1e594176bd3c'	System	17 Sep 2020 02:10:41
User entered 'No (N)'	System	17 Sep 2020 02:10:41

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:55

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:39', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'be0babe9-ed48-4c70-80fe-1e594176bd3c'	System	17 Sep 2020 02:10:41
User entered '16 Sep 2020 21:10'	System	17 Sep 2020 02:10:41

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

FDA-CBER-2022-1614-2824281

US3342256
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 4'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:05', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'd6330acc-abbf-4e34-9f49-391793c4a934'	System	18 Sep 2020 08:49:19
User entered 'Yes (Y)'	System	18 Sep 2020 08:49:19

US3342256
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:06:55

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:11', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'd6330acc-abbf-4e34-9f49-391793c4a934'	System	18 Sep 2020 08:49:19
User entered '97.3'	System	18 Sep 2020 08:49:19

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:14', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'd6330acc-abbf-4e34-9f49-391793c4a934'	System	18 Sep 2020 08:49:19
User entered 'No (N)'	System	18 Sep 2020 08:49:19

US3342256
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:06:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:17', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'd6330acc-abbf-4e34-9f49-391793c4a934'	System	18 Sep 2020 08:49:19
User entered '18 Sep 2020 03:49'	System	18 Sep 2020 08:49:19

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 5'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:04:29', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'a21d4b85-28ae-4610-9b23-efb3d2db7bad'	System	19 Sep 2020 01:04:44
User entered 'Yes (Y)'	System	19 Sep 2020 01:04:44

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:55

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:04:35', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'a21d4b85-28ae-4610-9b23-efb3d2db7bad'	System	19 Sep 2020 01:04:44
User entered '98.5'	System	19 Sep 2020 01:04:44

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:04:38', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'a21d4b85-28ae-4610-9b23-efb3d2db7bad'	System	19 Sep 2020 01:04:44
User entered 'No (N)'	System	19 Sep 2020 01:04:44

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:55

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:04:41', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'a21d4b85-28ae-4610-9b23-efb3d2db7bad'	System	19 Sep 2020 01:04:44
User entered '18 Sep 2020 20:04'	System	19 Sep 2020 01:04:44

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 6'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:21:46', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '565290ee-7a1d-45c9-bf66-919a6f4db4da'	System	20 Sep 2020 05:22:07
User entered 'Yes (Y)'	System	20 Sep 2020 05:22:07

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:55

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:21:51', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '565290ee-7a1d-45c9-bf66-919a6f4db4da'	System	20 Sep 2020 05:22:07
User entered '97.6'	System	20 Sep 2020 05:22:07

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:21:59', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '565290ee-7a1d-45c9-bf66-919a6f4db4da'	System	20 Sep 2020 05:22:07
User entered 'No (N)'	System	20 Sep 2020 05:22:07

US3342256
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:06:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:02', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '565290ee-7a1d-45c9-bf66-919a6f4db4da'	System	20 Sep 2020 05:22:07
User entered '20 Sep 2020 00:22'	System	20 Sep 2020 05:22:07

US3342256
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:25:37', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '0f0b72ff-8459-40cc-8d9c-11d886285ace'	System	14 Sep 2020 15:26:17
User entered 'None (1)'	System	14 Sep 2020 15:26:17

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:25:42', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '0f0b72ff-8459-40cc-8d9c-11d886285ace'	System	14 Sep 2020 15:26:17
User entered 'No (N)'	System	14 Sep 2020 15:26:17

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:25:45', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '0f0b72ff-8459-40cc-8d9c-11d886285ace'	System	14 Sep 2020 15:26:17
User entered 'No (N)'	System	14 Sep 2020 15:26:17

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:26:09', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '0f0b72ff-8459-40cc-8d9c-11d886285ace'	System	14 Sep 2020 15:26:17
User entered 'None (1)'	System	14 Sep 2020 15:26:17

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:06:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:26:12', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '0f0b72ff-8459-40cc-8d9c-11d886285ace'	System	14 Sep 2020 15:26:17
User entered '14 Sep 2020 10:26'	System	14 Sep 2020 15:26:17

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '14 Sep 2020 10:11'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '14 Sep 2020 12:41'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:25:50', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '9ae529ec-3ec7-47ef-ac23-0d1496d3f452'	System	15 Sep 2020 01:26:10
User entered 'None (1)'	System	15 Sep 2020 01:26:10

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:25:54', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '9ae529ec-3ec7-47ef-ac23-0d1496d3f452'	System	15 Sep 2020 01:26:10
User entered 'No (N)'	System	15 Sep 2020 01:26:10

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:25:57', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '9ae529ec-3ec7-47ef-ac23-0d1496d3f452'	System	15 Sep 2020 01:26:10
User entered 'No (N)'	System	15 Sep 2020 01:26:10

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:26:06', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '9ae529ec-3ec7-47ef-ac23-0d1496d3f452'	System	15 Sep 2020 01:26:10
User entered 'None (1)'	System	15 Sep 2020 01:26:10

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:06:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:26:09', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '9ae529ec-3ec7-47ef-ac23-0d1496d3f452'	System	15 Sep 2020 01:26:10
User entered '14 Sep 2020 20:26'	System	15 Sep 2020 01:26:10

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '14 Sep 2020 13:36'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:06:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 2'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:49:37', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '04efd8bb-70ff-4606-9b99-18206febc1e3'	System	16 Sep 2020 02:50:45
User entered 'None (1)'	System	16 Sep 2020 02:50:45

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:49:36', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '04efd8bb-70ff-4606-9b99-18206febc1e3'	System	16 Sep 2020 02:50:45
User entered 'No (N)'	System	16 Sep 2020 02:50:45

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:49:35', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '04efd8bb-70ff-4606-9b99-18206febc1e3'	System	16 Sep 2020 02:50:45
User entered 'No (N)'	System	16 Sep 2020 02:50:45

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:49:42', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '04efd8bb-70ff-4606-9b99-18206febc1e3'	System	16 Sep 2020 02:50:45
User entered 'None (1)'	System	16 Sep 2020 02:50:45

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:06:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:49:45', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '04efd8bb-70ff-4606-9b99-18206febc1e3'	System	16 Sep 2020 02:50:45
User entered '15 Sep 2020 21:49'	System	16 Sep 2020 02:50:45

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:06:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 3'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:42', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '6deeba4b-3d99-4ead-8e46-1924de661e52'	System	17 Sep 2020 02:10:53
User entered 'None (1)'	System	17 Sep 2020 02:10:53

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:44', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '6deeba4b-3d99-4ead-8e46-1924de661e52'	System	17 Sep 2020 02:10:53
User entered 'No (N)'	System	17 Sep 2020 02:10:53

FDA-CBER-2022-1614-2824329

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:46', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '6deeba4b-3d99-4ead-8e46-1924de661e52'	System	17 Sep 2020 02:10:53
User entered 'No (N)'	System	17 Sep 2020 02:10:53

FDA-CBER-2022-1614-2824330

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:48', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '6deeba4b-3d99-4ead-8e46-1924de661e52'	System	17 Sep 2020 02:10:53
User entered 'None (1)'	System	17 Sep 2020 02:10:53

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:55

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:50', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '6deeba4b-3d99-4ead-8e46-1924de661e52'	System	17 Sep 2020 02:10:53
User entered '16 Sep 2020 21:10'	System	17 Sep 2020 02:10:53

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:06:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 4'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:20', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '7b66804a-6207-41a3-8002-543540183361'	System	18 Sep 2020 08:49:39
User entered 'None (1)'	System	18 Sep 2020 08:49:39

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US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:23', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '7b66804a-6207-41a3-8002-543540183361'	System	18 Sep 2020 08:49:39
User entered 'No (N)'	System	18 Sep 2020 08:49:39

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:26', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '7b66804a-6207-41a3-8002-543540183361'	System	18 Sep 2020 08:49:39
User entered 'No (N)'	System	18 Sep 2020 08:49:39

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:33', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '7b66804a-6207-41a3-8002-543540183361'	System	18 Sep 2020 08:49:39
User entered 'None (1)'	System	18 Sep 2020 08:49:39

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:55

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:36', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '7b66804a-6207-41a3-8002-543540183361'	System	18 Sep 2020 08:49:39
User entered '18 Sep 2020 03:49'	System	18 Sep 2020 08:49:39

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:06:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 5'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:04:45', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e3958075-c42b-4748-8fde-d251c72f9b2b'	System	19 Sep 2020 01:04:59
User entered 'None (1)'	System	19 Sep 2020 01:04:59

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:04:47', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e3958075-c42b-4748-8fde-d251c72f9b2b'	System	19 Sep 2020 01:04:59
User entered 'No (N)'	System	19 Sep 2020 01:04:59

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:04:49', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e3958075-c42b-4748-8fde-d251c72f9b2b'	System	19 Sep 2020 01:04:59
User entered 'No (N)'	System	19 Sep 2020 01:04:59

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:04:51', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e3958075-c42b-4748-8fde-d251c72f9b2b'	System	19 Sep 2020 01:04:59
User entered 'None (1)'	System	19 Sep 2020 01:04:59

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:55

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:04:54', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e3958075-c42b-4748-8fde-d251c72f9b2b'	System	19 Sep 2020 01:04:59
User entered '18 Sep 2020 20:04'	System	19 Sep 2020 01:04:59

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:06:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:06:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 6'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:07', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e22204fc-e933-4557-9dc1-6d130b5f9d74'	System	20 Sep 2020 05:22:19
User entered 'None (1)'	System	20 Sep 2020 05:22:19

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:09', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e22204fc-e933-4557-9dc1-6d130b5f9d74'	System	20 Sep 2020 05:22:19
User entered 'No (N)'	System	20 Sep 2020 05:22:19

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:11', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e22204fc-e933-4557-9dc1-6d130b5f9d74'	System	20 Sep 2020 05:22:19
User entered 'No (N)'	System	20 Sep 2020 05:22:19

FDA-CBER-2022-1614-2824354

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:12', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e22204fc-e933-4557-9dc1-6d130b5f9d74'	System	20 Sep 2020 05:22:19
User entered 'None (1)'	System	20 Sep 2020 05:22:19

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:06:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:14', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e22204fc-e933-4557-9dc1-6d130b5f9d74'	System	20 Sep 2020 05:22:19
User entered '20 Sep 2020 00:22'	System	20 Sep 2020 05:22:19

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:06:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:06:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:06:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:26:16', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'ee9f9191-f041-4c4f-855d-4dc1bd6bf407'	System	14 Sep 2020 15:26:35
User entered 'None (0)'	System	14 Sep 2020 15:26:35

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:06:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:26:19', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'ee9f9191-f041-4c4f-855d-4dc1bd6bf407'	System	14 Sep 2020 15:26:35
User entered 'None (0)'	System	14 Sep 2020 15:26:35

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:26:21', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'ee9f9191-f041-4c4f-855d-4dc1bd6bf407'	System	14 Sep 2020 15:26:35
User entered 'None (0)'	System	14 Sep 2020 15:26:35

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:26:22', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'ee9f9191-f041-4c4f-855d-4dc1bd6bf407'	System	14 Sep 2020 15:26:35
User entered 'None (0)'	System	14 Sep 2020 15:26:35

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:06:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:26:24', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'ee9f9191-f041-4c4f-855d-4dc1bd6bf407'	System	14 Sep 2020 15:26:35
User entered 'None (0)'	System	14 Sep 2020 15:26:35

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:06:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:26:26', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'ee9f9191-f041-4c4f-855d-4dc1bd6bf407'	System	14 Sep 2020 15:26:35
User entered 'None (0)'	System	14 Sep 2020 15:26:35

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:26:30', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'ee9f9191-f041-4c4f-855d-4dc1bd6bf407'	System	14 Sep 2020 15:26:35
User entered 'No (N)'	System	14 Sep 2020 15:26:35

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:06:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T10:26:32', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'ee9f9191-f041-4c4f-855d-4dc1bd6bf407'	System	14 Sep 2020 15:26:35
User entered '14 Sep 2020 10:26'	System	14 Sep 2020 15:26:35

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '14 Sep 2020 10:11'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '14 Sep 2020 12:41'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:06:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:26:13', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '02f0615f-9673-4039-a9d7-bcbe3145055b'	System	15 Sep 2020 01:26:35
User entered 'None (0)'	System	15 Sep 2020 01:26:35

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:06:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:26:16', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '02f0615f-9673-4039-a9d7-bcbe3145055b'	System	15 Sep 2020 01:26:35
User entered 'None (0)'	System	15 Sep 2020 01:26:35

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:26:18', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '02f0615f-9673-4039-a9d7-bcbe3145055b'	System	15 Sep 2020 01:26:35
User entered 'None (0)'	System	15 Sep 2020 01:26:35

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:26:20', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '02f0615f-9673-4039-a9d7-bcbe3145055b'	System	15 Sep 2020 01:26:35
User entered 'None (0)'	System	15 Sep 2020 01:26:35

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:06:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:26:23', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '02f0615f-9673-4039-a9d7-bcbe3145055b'	System	15 Sep 2020 01:26:35
User entered 'None (0)'	System	15 Sep 2020 01:26:35

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:06:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:26:25', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '02f0615f-9673-4039-a9d7-bcbe3145055b'	System	15 Sep 2020 01:26:35
User entered 'None (0)'	System	15 Sep 2020 01:26:35

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:26:31', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '02f0615f-9673-4039-a9d7-bcbe3145055b'	System	15 Sep 2020 01:26:35
User entered 'No (N)'	System	15 Sep 2020 01:26:35

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:06:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-14T20:26:34', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '02f0615f-9673-4039-a9d7-bcbe3145055b'	System	15 Sep 2020 01:26:35
User entered '14 Sep 2020 20:26'	System	15 Sep 2020 01:26:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '14 Sep 2020 13:36'	System	14 Sep 2020 15:14:42

FDA-CBER-2022-1614-2824379

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

FDA-CBER-2022-1614-2824380

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 2'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:06:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:49:53', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '4ad2c626-cb03-4704-b048-491c41b82982'	System	16 Sep 2020 02:51:04
User entered 'None (0)'	System	16 Sep 2020 02:51:04

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:49:56', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '4ad2c626-cb03-4704-b048-491c41b82982'	System	16 Sep 2020 02:51:04
User entered 'None (0)'	System	16 Sep 2020 02:51:04

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:06:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:50:00', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '4ad2c626-cb03-4704-b048-491c41b82982'	System	16 Sep 2020 02:51:04
User entered 'None (0)'	System	16 Sep 2020 02:51:04

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:50:05', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '4ad2c626-cb03-4704-b048-491c41b82982'	System	16 Sep 2020 02:51:04
User entered 'None (0)'	System	16 Sep 2020 02:51:04

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:06:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:50:08', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '4ad2c626-cb03-4704-b048-491c41b82982'	System	16 Sep 2020 02:51:04
User entered 'None (0)'	System	16 Sep 2020 02:51:04

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:50:10', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '4ad2c626-cb03-4704-b048-491c41b82982'	System	16 Sep 2020 02:51:04
User entered 'None (0)'	System	16 Sep 2020 02:51:04

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:50:14', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '4ad2c626-cb03-4704-b048-491c41b82982'	System	16 Sep 2020 02:51:04
User entered 'No (N)'	System	16 Sep 2020 02:51:04

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:55

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-15T21:50:17', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '4ad2c626-cb03-4704-b048-491c41b82982'	System	16 Sep 2020 02:51:04
User entered '15 Sep 2020 21:50'	System	16 Sep 2020 02:51:04

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 3'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:53', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e0c41086-b00b-4144-b011-bd0c678e6bd6'	System	17 Sep 2020 02:11:07
User entered 'None (0)'	System	17 Sep 2020 02:11:07

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:06:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:55', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e0c41086-b00b-4144-b011-bd0c678e6bd6'	System	17 Sep 2020 02:11:07
User entered 'None (0)'	System	17 Sep 2020 02:11:07

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:56', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e0c41086-b00b-4144-b011-bd0c678e6bd6'	System	17 Sep 2020 02:11:07
User entered 'None (0)'	System	17 Sep 2020 02:11:07

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:57', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e0c41086-b00b-4144-b011-bd0c678e6bd6'	System	17 Sep 2020 02:11:07
User entered 'None (0)'	System	17 Sep 2020 02:11:07

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:06:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:10:59', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e0c41086-b00b-4144-b011-bd0c678e6bd6'	System	17 Sep 2020 02:11:07
User entered 'None (0)'	System	17 Sep 2020 02:11:07

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:06:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:11:00', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e0c41086-b00b-4144-b011-bd0c678e6bd6'	System	17 Sep 2020 02:11:07
User entered 'None (0)'	System	17 Sep 2020 02:11:07

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:11:02', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e0c41086-b00b-4144-b011-bd0c678e6bd6'	System	17 Sep 2020 02:11:07
User entered 'No (N)'	System	17 Sep 2020 02:11:07

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:55

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-16T21:11:04', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'e0c41086-b00b-4144-b011-bd0c678e6bd6'	System	17 Sep 2020 02:11:07
User entered '16 Sep 2020 21:11'	System	17 Sep 2020 02:11:07

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

FDA-CBER-2022-1614-2824401

Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:06:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 4'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:39', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '459fb9b6-1e5e-4071-82a9-1ef61b3e534a'	System	18 Sep 2020 08:49:56
User entered 'None (0)'	System	18 Sep 2020 08:49:56

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:06:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:41', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '459fb9b6-1e5e-4071-82a9-1ef61b3e534a'	System	18 Sep 2020 08:49:56
User entered 'None (0)'	System	18 Sep 2020 08:49:56

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:43', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '459fb9b6-1e5e-4071-82a9-1ef61b3e534a'	System	18 Sep 2020 08:49:56
User entered 'None (0)'	System	18 Sep 2020 08:49:56

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:06:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:45', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '459fb9b6-1e5e-4071-82a9-1ef61b3e534a'	System	18 Sep 2020 08:49:56
User entered 'None (0)'	System	18 Sep 2020 08:49:56

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:06:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:47', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '459fb9b6-1e5e-4071-82a9-1ef61b3e534a'	System	18 Sep 2020 08:49:56
User entered 'None (0)'	System	18 Sep 2020 08:49:56

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:06:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:49', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '459fb9b6-1e5e-4071-82a9-1ef61b3e534a'	System	18 Sep 2020 08:49:56
User entered 'None (0)'	System	18 Sep 2020 08:49:56

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:51', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '459fb9b6-1e5e-4071-82a9-1ef61b3e534a'	System	18 Sep 2020 08:49:56
User entered 'No (N)'	System	18 Sep 2020 08:49:56

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:55

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T03:49:54', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '459fb9b6-1e5e-4071-82a9-1ef61b3e534a'	System	18 Sep 2020 08:49:56
User entered '18 Sep 2020 03:49'	System	18 Sep 2020 08:49:56

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:06:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 5'	System	14 Sep 2020 15:14:42

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:06:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:04:59', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'be227b8f-5ea1-44f5-ba01-f9068adf82b5'	System	19 Sep 2020 01:05:25
User entered 'None (0)'	System	19 Sep 2020 01:05:25

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:06:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:05:02', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'be227b8f-5ea1-44f5-ba01-f9068adf82b5'	System	19 Sep 2020 01:05:25
User entered 'None (0)'	System	19 Sep 2020 01:05:25

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:06:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:05:08', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'be227b8f-5ea1-44f5-ba01-f9068adf82b5'	System	19 Sep 2020 01:05:25
User entered 'No interference with activity (1)'	System	19 Sep 2020 01:05:25

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:06:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:05:10', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'be227b8f-5ea1-44f5-ba01-f9068adf82b5'	System	19 Sep 2020 01:05:25
User entered 'No interference with activity (1)'	System	19 Sep 2020 01:05:25

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:06:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:05:12', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'be227b8f-5ea1-44f5-ba01-f9068adf82b5'	System	19 Sep 2020 01:05:25
User entered 'None (0)'	System	19 Sep 2020 01:05:25

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:06:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:05:15', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'be227b8f-5ea1-44f5-ba01-f9068adf82b5'	System	19 Sep 2020 01:05:25
User entered 'No interference with activity (1)'	System	19 Sep 2020 01:05:25

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:05:18', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'be227b8f-5ea1-44f5-ba01-f9068adf82b5'	System	19 Sep 2020 01:05:25
User entered 'No (N)'	System	19 Sep 2020 01:05:25

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:55

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-18T20:05:21', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: 'be227b8f-5ea1-44f5-ba01-f9068adf82b5'	System	19 Sep 2020 01:05:25
User entered '18 Sep 2020 20:05'	System	19 Sep 2020 01:05:25

Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

FDA-CBER-2022-1614-2824424

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
Data entry locked.	System	14 Sep 2020 15:14:42
User entered 'Day 6'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:18', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '8694c69a-133f-461f-9168-d4fabdb9a9d1'	System	20 Sep 2020 05:22:36
User entered 'None (0)'	System	20 Sep 2020 05:22:36

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:19', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '8694c69a-133f-461f-9168-d4fabdb9a9d1'	System	20 Sep 2020 05:22:36
User entered 'None (0)'	System	20 Sep 2020 05:22:36

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:20', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '8694c69a-133f-461f-9168-d4fabdb9a9d1'	System	20 Sep 2020 05:22:36
User entered 'None (0)'	System	20 Sep 2020 05:22:36

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:21', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '8694c69a-133f-461f-9168-d4fabdb9a9d1'	System	20 Sep 2020 05:22:36
User entered 'None (0)'	System	20 Sep 2020 05:22:36

US3342256
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:06:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:22', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '8694c69a-133f-461f-9168-d4fabdb9a9d1'	System	20 Sep 2020 05:22:36
User entered 'None (0)'	System	20 Sep 2020 05:22:36

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:23', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '8694c69a-133f-461f-9168-d4fabdb9a9d1'	System	20 Sep 2020 05:22:36
User entered 'None (0)'	System	20 Sep 2020 05:22:36

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:30', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '8694c69a-133f-461f-9168-d4fabdb9a9d1'	System	20 Sep 2020 05:22:36
User entered 'No (N)'	System	20 Sep 2020 05:22:36

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:55

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9656E2DD-ED63-4456-9521-94CD0BBF17ED)', Time: '2020-09-20T00:22:32', User OID: 'PatientReportedOutcome (US3342256)', ODM File OID: '8694c69a-133f-461f-9168-d4fabdb9a9d1'	System	20 Sep 2020 05:22:36
User entered '20 Sep 2020 00:22'	System	20 Sep 2020 05:22:36

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:27:14
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:06:55

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 15:32:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:16:31
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	25 Sep 2020 13:04:32

US3342256

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:55

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 15:32:02
User closed query ' Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 12:41:02
Query ' Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction' answered with 'site was not notified of patient's death until later. date entered reflects the attempt made to contact subject' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	23 Mar 2021 15:49:20
User opened query ' Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:03:14
Query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4), (b) (6)	22 Mar 2021 16:03:09
Query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	22 Mar 2021 16:03:08
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:16:31
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	09 Oct 2020 15:14:36
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Oct 2020 15:11:25
User entered '24 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	25 Sep 2020 13:04:32

US3342256

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:55

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:32:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:16:31
User entered 'Contact Not Made (CONTACT NOT MADE)'	Ethan Shotton (b) (4) (b) (4)	25 Sep 2020 13:04:32

US3342256

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:55

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:32:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:16:31
User entered 'Left a voicemail once each day from 21Sep2020 to 24Sep2020. Also sent an email on 23Sep2020.'	Ethan Shotton (b) (4) (b) (4)	25 Sep 2020 13:04:32

Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:06:55

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:22:29
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	25 Sep 2020 13:04:38

US3342256

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:55

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '1'	System	25 Sep 2020 13:04:38

US3342256
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:06:55

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:16:18
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	01 Oct 2020 22:37:23
	(b) (4)	

US3342256
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:06:55

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:45:47
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:45:41
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:16:18
Query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile. ' answered with 'site was not notified of patient's death until later. date entered reflects the attempt made to contact subject ' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 22:48:27
Query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction. ' answered with 'site was not notified of patient's death until later. date entered reflects the attempt made to contact subject ' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 22:48:25
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:46:14
Query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:46:07
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:46:03
Query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:45:57

US3342256
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:06:55

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	10 Nov 2020 17:26:52
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Nov 2020 17:26:52
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Nov 2020 17:26:52
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	10 Nov 2020 17:26:52
User entered '01 Oct 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 17:26:52
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	09 Oct 2020 15:14:36
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Oct 2020 15:11:25
User entered '1 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	01 Oct 2020 22:37:23

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:16:18
User entered 'Contact Not Made (CONTACT NOT MADE)'	Ethan Shotton (b) (4) (b) (4)	01 Oct 2020 22:37:23

US3342256

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:55

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:16:18
User entered 'Left a voicemail once each day from 29Sep2020 - 01Oct2020. Also sent a text reminder on 01Oct2020.'	Ethan Shotton (b) (4) (b) (4)	01 Oct 2020 22:37:23

US3342256

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:55

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:04:11
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	01 Oct 2020 22:37:26

US3342256
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:06:55
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered '1'	System	01 Oct 2020 22:37:26

US3342256
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:06:55

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:32:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:05:56
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	08 Oct 2020 16:29:38

US3342256

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:55

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 15:32:02
User closed query ' Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 12:40:05
Query ' Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction' answered with 'site was not notified of patient's death until later. date entered reflects the attempt made to contact subject' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	23 Mar 2021 15:49:24
User opened query ' Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 15:51:02
Query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	22 Mar 2021 15:50:57
Query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4), (b) (6)	22 Mar 2021 15:50:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:05:56
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	10 Nov 2020 17:27:04
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Nov 2020 17:27:04

US3342256

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:55

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Nov 2020 17:27:04
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	10 Nov 2020 17:27:04
User entered '08 Oct 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 17:27:04
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	09 Oct 2020 15:14:36
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Oct 2020 15:11:25
User entered '8 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:29:38

US3342256
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:06:55

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:32:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:05:56
User entered 'Contact Not Made (CONTACT NOT MADE)'	Eileen Euperio (b) (4)	08 Oct 2020 16:29:38
	(b) (4)	

Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:06:55
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 15:32:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:05:56
User entered 'See SAE narrative regarding death'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:29:38

US3342256

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:55

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:05:46
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:29:43

US3342256

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:55

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:56:45
User entered empty.	System	08 Oct 2020 16:29:43

US3342256

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:06:55

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:56
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	08 Oct 2020 15:26:49
	(b) (4)	

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:30
User entered 'USA-US203-2020-mRNA-1273-P301000003'	System	08 Oct 2020 15:54:27
User entered 'New'	(b) (4), (b) (6)	08 Oct 2020 15:54:27

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:19:05
User closed query 'PV Query: The event term 'Suspected cardiopulmonary arrest due to acute myocardial infarction' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:01:40
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Cardio-respiratory arrest, LLT: Cardiopulmonary arrest - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:19:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:19:30
Data point term sent to Coder	System	27 Oct 2020 22:18:30
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Cardio-respiratory arrest, LLT: Cardiopulmonary arrest - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:18:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:18:29
Query 'For coding purposes, please split SUSPECTED CARDIOPULMONARY ARREST DUE TO ACUTE MYOCARDIAL INFARCTION into separate entries. 1. SUSPECTED CARDIOPULMONARY ARREST [DUE TO ACUTE MYOCARDIAL INFARCTION] and 2. ACUTE MYOCARDIAL INFARCTION' canceled (Site from System).	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:18:25
Query 'PV Query: The event term 'Suspected cardiopulmonary arrest due to acute myocardial infarction' contains multiple event terms. Please consider separating them into separate events.' answered with 'updated' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 22:18:12
Data point term sent to Coder	System	27 Oct 2020 22:17:29
DataPoint Un-verified.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 22:17:27

US3342256
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:06:55
Adverse event

Audit	User	Time (GMT)
Coding entries removed.	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 22:17:27
User entered 'CARDIOPULMONARY ARREST' reason for change: Per Query Resolution	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 22:17:27
User opened query 'For coding purposes, please split SUSPECTED CARDIOPULMONARY ARREST DUE TO ACUTE MYOCARDIAL INFARCTION into separate entries. 1. SUSPECTED CARDIOPULMONARY ARREST [DUE TO ACUTE MYOCARDIAL INFARCTION] and 2. ACUTE MYOCARDIAL INFARCTION' (Site from System).	Coder Import (b) (4) (b) (4)	27 Oct 2020 18:18:23
User opened query 'PV Query: The event term 'Suspected cardiopulmonary arrest due to acute myocardial infarction' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:35:46
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Cardio-respiratory arrest, LLT: Cardiopulmonary arrest - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 07:29:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 07:29:23
Data point term sent to Coder	System	08 Oct 2020 15:32:23
User entered 'suspected cardiopulmonary arrest due to acute myocardial infarction'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	08 Oct 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered '20 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered empty.	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered empty.	System	08 Oct 2020 15:31:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'No (N)'	Eileen Euperio (b) (4)	08 Oct 2020 15:31:48
	(b) (4)	

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered '20 Sep 2020'	Eileen Euperio (b) (4)	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered empty.	Eileen Euperio (b) (4)	08 Oct 2020 15:31:48
	(b) (4)	

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered empty.	System	08 Oct 2020 15:31:48

US3342256
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:06:55

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'Grade 4 (Grade 4)'	Eileen Euperio (b) (4)	08 Oct 2020 15:31:48
	(b) (4)	

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered '1'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered '0'	Eileen Euperio (b) (4)	08 Oct 2020 15:31:48
	(b) (4)	

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered '0'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered empty.	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered empty.	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

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Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered empty.	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

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Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered empty.	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered '0'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered '0'	Eileen Euperio (b) (4)	08 Oct 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered '0'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

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Folder: Adverse Events

Form: Adverse Events (1)

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Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'Not Related (NOT RELATED)'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

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Folder: Adverse Events

Form: Adverse Events (1)

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Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'Not Related (NOT RELATED)'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Query 'Per CDM: Subject died on 20Sep2020 and only one IP was done. Please consider changing this answer from "Not Applicable" to "Investigational Product Withdrawn". Thank you!' canceled (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:21:31
User opened query 'Per CDM: Subject died on 20Sep2020 and only one IP was done. Please consider changing this answer from "Not Applicable" to "Investigational Product Withdrawn". Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:20:37
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'Not Applicable (NOT APPLICABLE)'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:06:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Oct 2020 15:32:15
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Oct 2020 15:31:48
User entered '0'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:06:55
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User closed query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:48:39
Query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'site has received medical examiner report but unfortunately unable to obtain medical records from event. Conmed is assumed as subject had resuscitation attempts, but no formal records of medication used are available.' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:49:15
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:49:39
User closed query 'Per CDM: "Concomitant Medication" has been added for this AE, however there is no Medication with the Indication of "Cardio-respiratory arrest". Please review and update or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 12:03:17

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Form: Adverse Events (1)

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Concomitant Medication

Audit	User	Time (GMT)
Query 'Per CDM: "Concomitant Medication" has been added for this AE, however there is no Medication with the Indication of "Cardio-respiratory arrest". Please review and update or update accordingly. ' answered with 'we have not received med records yet ' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 22:19:52
User opened query 'Per CDM: "Concomitant Medication" has been added for this AE, however there is no Medication with the Indication of "Cardio-respiratory arrest". Please review and update or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:45:46
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered '1' reason for change: Per Query Resolution	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:32:15
User entered '0'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

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Folder: Adverse Events

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Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that macth this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 13:43:52
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that macth this AE during this timeframe. Review and update eCRF as appropriate.' answered with 'updated, con procedures are listed in CRF' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:35:23
DataPoint Un-verified.	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:34:45
User entered '1' reason for change: Per Query Resolution	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:34:45
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that macth this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 02:09:34
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered '0'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

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Form: Adverse Events (1)

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Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'Fatal (FATAL)'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:06:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered empty.	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User closed query 'PV Query: Please consider updating the event term (s) to the cause of death per the ME report.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:53:04
User closed query 'PV Query: Please send a hospital discharge summary, medical records and autopsy results 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)	26 Feb 2021 17:52:59
User closed query 'Per DM CLR: Narrative = LV HYPERTROPHY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 13:44:19
User closed query 'Per DM CLR: Narrative = HYPERTENSIVE CARDIOVASCULAR DISEASE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 13:44:16
Query 'Per DM CLR: Narrative = LV HYPERTROPHY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'NOT a separate AE, this is captured in med Hx' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:49:42
Query 'Per DM CLR: Narrative = HYPERTENSIVE CARDIOVASCULAR DISEASE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'not a separate AE, this is reflected in ongoing med hx' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:36:20

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Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary, medical records and autopsy results 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 'only autopsy results were obtained; these have been sent via fax 28Jan2021' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:34:27
Query 'PV Query: Please consider updating the event term (s) to the cause of death per the ME report.' answered with 'Cause of death site received from ME reports atherosclerosis and stenosis of coronary vessels that likely CONTRIBUTED to MI. The event itself to remain cardiopulmonary arrest' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	25 Feb 2021 20:33:47
User opened query 'Per DM CLR: Narrative = LV HYPERTROPHY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 02:09:27
User opened query 'Per DM CLR: Narrative = HYPERTENSIVE CARDIOVASCULAR DISEASE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 02:09:22
User opened query 'PV Query: Please consider updating the event term (s) to the cause of death per the ME report.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 20:08:43
Query 'SQ Query: Please consider updating the event term (s) to the cause of death per the ME report.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 20:08:36
User opened query 'PV Query: Please send a hospital discharge summary, medical records and autopsy results 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)	04 Feb 2021 20:07:28
User opened query 'SQ Query: Please consider updating the event term (s) to the cause of death per the ME report.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 20:05:20

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Narrative

Audit	User	Time (GMT)
User entered 'SUBJECT'S SPOUSE CALLED SITE 08OCT2020 TO INFORM OF PASSING OF SUBJECT ON 20SEP2020 DUE TO MI; SPOUSE STATES THAT PATIENT HAD HISTORY OF HEART DISEASE. SITE PENDING MEDICAL RECORDS AND AUTOPSY REPORT. CONMED ADMINISTRATION UNKNOWN AT TIME OF INITIAL REPORT. SITE RECEIVED MEDICAL EXAMINER RECORDS 26JAN2021. CAUSE OF DEATH STATEMENT STATES ARTHEROSCLEROTIC AND HYPERTENSIVE CARDIOVASCULAR DISEASE, MANNER OF DEATH NATURAL. REPORT STATES 43-Y/O MAN WAS WITNESSED COLLAPSE IN ER WHERE HE PRESENTED BY PRIVATE VEHICLE W/ CHEST PAIN AND SOB. RESUSCITATION UNSUCCESSFUL. AUTOPSY SHOWED CARDIOMEGALY, LV HYPERTROPHY, ARTHEROSCLEROSIS AND STENOSIS OF CORONARY ARTERIES, WITH ARTERIOLENEPHROSCLEROSIS WHICH IS COMMONLY SEEN IN THOSE WITH HIGH BP. POSTMORTEM TOXICOLOGY SHOWED PRESENCE OF ETOH 0.05% FEMORAL BLOOD AND 0.06% VITREOUS. EVIDENCE OF MEDICAL INTERVENTION INCLUDE ENDOTRACHEAL TUBE, DEFIBRILLATOR PADS AFFIXED TO TORSO, ECG AFFIXED TO TORSO AND UPPER EXTREMITIES, INTRAVASCULAR CATHETER FROM R ANTECUBITAL FOSSA,; INJURIES RELATED TO RESUSCITATIVE ATTEMPTS SHOW BL ANTEROLATERAL RIB FRACTURES WITH ASSOC. INTERCOSTAL MUSCLE HEMORRHAGE AND PANCREATIC HEMORRHAGE. POSTMORTEM CT ADDITIONALLY REVEALED CARDIOMEGALY AND FOCAL CORONARY ARTERY CALCIFICATION' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 16:38:34

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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:23:11
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)	29 Jan 2021 20:22:58
User closed query 'PV Query: Per subject's spouse, the subject had a history of heart disease. Please specify type of heart disease and consider updating the subject's medical history accordingly.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:22:51
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)	29 Jan 2021 20:22:40
User closed query 'PV Query: Please send a hospital discharge summary, medical records and autopsy results 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)	29 Jan 2021 20:22:32
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:22:28
User closed query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. SAE Narrative = PATIENT HAD HISTORY OF HEART DISEASE. However, this is not recorded in the Med History eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:51:45

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Narrative

Audit	User		Time (GMT)
Query 'PV Query: Per subject's spouse, the subject had a history of heart disease. Please specify type of heart disease and consider updating the subject's medical history accordingly.' answered with 'coronary heart disease (artherosclerosis of coronary arteries) has been added to hx and narrative' (Site from Safety).	Eileen Euperio	(b) (4) (b) (4)	28 Jan 2021 22:52:33
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 'narrative has ben updated along with con procedures' (Site from Safety).	Eileen Euperio	(b) (4) (b) (4)	28 Jan 2021 22:52:00
Query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. SAE Narrative = PATIENT HAD HISTORY OF HEART DISEASE. However, this is not recorded in the Med History eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'med hx CRF has been updated based on new reports received' (Site from DM).	Eileen Euperio	(b) (4) (b) (4)	28 Jan 2021 22:49:33
Query 'PV Query: Please send a hospital discharge summary, medical records and autopsy results 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 'INFORMATION HAS BEEN SENT VIA FAX' (Site from Safety).	Eileen Euperio	(b) (4) (b) (4)	28 Jan 2021 22:17:04
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'UPDATED IN NARRATIVE' (Site from Safety).	Eileen Euperio	(b) (4) (b) (4)	28 Jan 2021 21:14:31

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Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'NARRATIVE IS UPDATED WITH INFO FROM TESTS PER MEDICAL EXAMINER' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 21:14:24
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'COVID-19 TEST NOT SHOWN IN RECORDS OBTAINED FROM MEDICAL EXAMINER.' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 21:13:38
DataPoint Un-verified.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 21:12:52

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Narrative

Audit	User	Time (GMT)
User entered 'SUBJECT'S SPOUSE CALLED SITE 08OCT2020 TO INFORM OF PASSING OF SUBJECT ON 20SEP2020 DUE TO MI; SPOUSE STATES THAT PATIENT HAD HISTORY OF HEART DISEASE. SITE PENDING MEDICAL RECORDS AND AUTOPSY REPORT. CONMED ADMINISTRATION UNKNOWN AT TIME OF INITIAL REPORT. SITE RECEIVED MEDICAL EXAMINER RECORDS 26JAN2021. CAUSE OF DEATH STATEMENT STATES ARTHEROSCLEROTIC AND HYPERTENSIVE CARDIOVASCULAR DISEASE, MANNER OF DEATH NATURAL. REPORT STATES 43-Y/O MAN WAS WITNESSED COLLAPSE IN ER WHERE HE PRESENTED BY PRIVATE VEHICLE W/ CHEST PAIN AND SOB. RESUSCITATION UNSUCCESSFUL. AUTOPY SHOWED CARDIOMEGALY, LV HYPERTROPHY, ARTHEROSCLEROSIS AND STENOSIS OF CORONARY ARTERIES, WITH ARTERIOLENEPHROSCLEROSIS WHICH IS COMMONLY SEEN IN THOSE WITH HIGH BP. POSTMORTEM TOXICOLOGY SHOWED PRESENCE OF ETOH 0.05% FEMORAL BLOOD AND 0.06% VITREOUS. EVIDENCE OF MEDICAL INTERVENTION INCLUDE ENDOTRACHEAL TUBE, DEFIBRILLATOR PADS AFFIXED TO TORSO, ECG AFFIXED TO TORSO AND UPPER EXTREMITIES, INTRAVASCULAR CATHETER FROM R ANTECUBITAL FOSSA,; INJURIES RELATED TO RESUSCITATIVE ATTEMPTS SHOW BL ANTEROLATERAL RIB FRACTURES WITH ASSOC. INTERCOSTAL MUSCLE HEMORRHAGE AND PANCREATIC HEMORRHAGE. POSTMORTEM CT ADDITIONALLY REVEALED CARDIOMEGALY AND FOCAL CORONARY ARTERY CALCIFICATION' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 21:12:52

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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Is it known whether the subject passed away at home or in the hospital?' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:20:17
Query 'PV Query: Is it known whether the subject passed away at home or in the hospital?' answered with 'reported to site that subject passed away in hospital' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:32:06
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:17:10
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 Nov 2020 17:17:01
User opened query 'PV Query: Per subject's spouse, the subject had a history of heart disease. Please specify type of heart disease and consider updating the subject's medical history accordingly.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:16:52
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 Nov 2020 17:16:40
User opened query 'PV Query: Please send a hospital discharge summary, medical records and autopsy results 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)	16 Nov 2020 17:16:28
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:16:09
User opened query 'PV Query: Is it known whether the subject passed away at home or in the hospital?' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:15:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary, medical records and autopsy results 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)	11 Nov 2020 19:45:03
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)	11 Nov 2020 19:44:58
User closed query 'PV Query: Per subject's spouse, the subject had a history of heart disease. Please specify type of heart disease and consider updating the subject's medical history accordingly.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:44:50
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)	11 Nov 2020 19:44:35
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:44:30
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. SAE Narrative = PATIENT HAD HISTORY OF HEART DISEASE. However, this is not recorded in the Med History eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:49:03

FDA-CBER-2022-1614-2824499

US3342256
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:06:55
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary, medical records and autopsy results 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 'unsuccessful attempts to contact subject's wife regarding medical records have been made; records not available at this time' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 23:01:28
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 'site still pending additional records. Attempts have been made to contact subject's wife for release of records but have not yet been successful.' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 22:51:23
Query 'PV Query: Per subject's spouse, the subject had a history of heart disease. Please specify type of heart disease and consider updating the subject's medical history accordingly.' answered with 'site still pending additional records. Attempts have been made to contact subject's wife for release of records but have not yet been successful.' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 22:51:18
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'site still pending additional records. Attempts have been made to contact subject's wife for release of records but have not yet been successful.' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 22:51:15
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'site still pending additional records. Attempts have been made to contact subject's wife for release of records but have not yet been successful.' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 22:51:13

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:16:55
User opened query 'PV Query: Per subject's spouse, the subject had a history of heart disease. Please specify type of heart disease and consider updating the subject's medical history accordingly.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:16:09
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)	06 Nov 2020 14:15:52
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:15:28
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)	28 Oct 2020 13:01:53
User closed query 'PV Query: Per subject's spouse, the subject had a history of heart disease. Please specify type of heart disease and consider updating the subject's medical history accordingly.' (Site from Safety).		28 Oct 2020 13:01:52
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Sit from Safety).		28 Oct 2020 13:01:48
User closed query 'PV Query: Please provide autops results if performed. If not performed, please state so.' (Site from Safety).		28 Oct 2020 13:01:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'pending' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 22:19:31
Query 'PV Query: Per subject's spouse, the subject had a history of heart disease. Please specify type of heart disease and consider updating the subject's medical history accordingly.' answered with 'pending detail' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 22:19:28
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 22:19:22
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'pending' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	27 Oct 2020 22:19:19
User opened query 'PV Query: Please send a hospital discharge summary, medical records and autopsy results 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)	16 Oct 2020 13:37:42
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 Oct 2020 13:36:53
User opened query 'PV Query: Per subject's spouse, the subject had a history of heart disease. Please specify type of heart disease and consider updating the subject's medical history accordingly.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:36:21

US3342256
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:06:55
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:36:04
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:35:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'SUBJECT'S SPOUSE CALLED SITE 08OCT2020 TO INFORM OF PASSING OF SUBJECT ON 20SEP2020 DUE TO MI; SPOUSE STATES THAT PATIENT HAD HISTORY OF HEART DISEASE. SITE PENDING MEDICAL RECORDS AND AUTOPSY REPORT. conmed administration unknown at time of initial report' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:32:48
User entered 'subject's spouse called site 08Oct2020 to inform of passing of subject on 20Sep2020 due to MI; spouse states that patient had history of heart disease. site pending medical records and autopsy report'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered '1'	System	08 Oct 2020 15:31:48

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered '1'	System	08 Oct 2020 15:31:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:55

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:59
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:49:54

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:32
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:52:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:52:46
Data point term sent to Coder	System	14 Sep 2020 14:51:26
User entered 'ADVIL'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered 'HEADACHES'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:06:55

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered '400'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered 'mg (mg)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered 'as needed (PRN)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered 'Oral (ORAL)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered empty.	Morgan Schulle (b) (4)	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 12:39:08
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'error, updated' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:30:57
DataPoint Un-verified.	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:30:50
User entered 'UN UNK 2008' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:30:50
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 21:45:37
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered 'UN UNK 2000'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:50:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered empty.	System	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered empty.	System	14 Sep 2020 14:50:57

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:55

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered empty.	System	14 Sep 2020 14:50:57

US3342256
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 17:06:55
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:39
User closed query 'Per CDM: Kindly review Indication for ConProc since none of the AE's recorded has the 'Concomitant procedure' option checked. Please reconcile and update as needed, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:08:00
Query 'Per CDM: Kindly review Indication for ConProc since none of the AE's recorded has the 'Concomitant procedure' option checked. Please reconcile and update as needed, else provide clarification.' answered with 'con procedures are checked off for AE USA-US203-2020-MRNA-1273-P301000003' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	18 Mar 2021 13:59:46
User opened query 'Per CDM: Kindly review Indication for ConProc since none of the AE's recorded has the 'Concomitant procedure' option checked. Please reconcile and update as needed, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 19:04:44
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:44:10

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:55

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered '20 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:44:41

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:55

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered 'endotracheal intubation'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:44:41

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:55

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
Query 'Per CDM: Indication = Adverse Event, however none of the AE's recorded has the 'Concomitant procedure' option checked. Please reconcile and update as needed, else provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 19:04:00
User opened query 'Per CDM: Indication = Adverse Event, however none of the AE's recorded has the 'Concomitant procedure' option checked. Please reconcile and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 19:03:36
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:44:41

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:44:41

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:55

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:08:52
User entered '20 Sep 2020'	Eileen Euperio (b) (4)	28 Jan 2021 22:44:55

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:55

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered 'defibrillation'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:44:55

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:55

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
Query 'Per CDM: Indication = Adverse Event, however none of the AE's recorded has the 'Concomitant procedure' option checked. Please reconcile and update as needed, else provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 19:03:57
User opened query 'Per CDM: Indication = Adverse Event, however none of the AE's recorded has the 'Concomitant procedure' option checked. Please reconcile and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 19:03:44
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:44:55

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:44:55

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:06:55

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered '20 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:45:17

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:06:55

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered 'electrocardiogram'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:45:17

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:06:55

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:45:17

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:08:52
User entered empty.	Eileen Euperio (b) (4)	28 Jan 2021 22:45:17

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:06:55

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered '20 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:45:56

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:06:55

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:08:52
User entered 'intravascular catheterization right antecubital fossa'	Eileen Euperio (b) (4)	28 Jan 2021 22:45:56

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:06:55

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:45:56

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:06:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:45:56

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:06:55

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User closed query ' Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 11:59:37
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
Query ' Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction. ' answered with 'procedure done post-mortem. per query resolution on AE procedure added as it was included on autopsy report. please remove query. thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 21:25:23
User opened query ' Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 15:47:12
Query 'Procedure Date is after Date of Death. Please review and provide any needed correction.' canceled (Site from System).	(b) (4), (b) (6)	22 Mar 2021 15:47:01
Query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4), (b) (6)	22 Mar 2021 15:46:58
User opened query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	28 Jan 2021 22:46:13
User opened query 'Procedure Date is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	28 Jan 2021 22:46:13
User entered '21 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:46:13

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered 'postmortem CT scan'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:46:13

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:06:55

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:46:13

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:06:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:08:52
User entered empty.	Eileen Euperio (b) (4)	28 Jan 2021 22:46:13

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:06:55

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User closed query ' Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 11:59:47
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
Query ' Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction. ' answered with 'procedure performed postmortem per query resolution procedure added as this was a part of the autopsy. please remove query. tha' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 21:27:31
User opened query ' Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 15:47:24
Query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4), (b) (6)	22 Mar 2021 15:47:19
Query 'Procedure Date is after Date of Death. Please review and provide any needed correction.' canceled (Site from System).	(b) (4), (b) (6)	22 Mar 2021 15:47:18
User opened query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	28 Jan 2021 22:46:34
User opened query 'Procedure Date is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	28 Jan 2021 22:46:34
User entered '02 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:46:34

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:06:55

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:08:52
User entered 'toxicology labs postmortem'	Eileen Euperio (b) (4)	28 Jan 2021 22:46:34

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:46:34

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:06:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 22:08:52
User entered empty.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:46:34

US3342256

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:06:55

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:57
User closed query 'Date of dosing discontinuation is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	09 Oct 2020 15:15:07
User closed query 'Date of dosing discontinuation is after date of death. Please update as appropriate.' (Site from System).	System	09 Oct 2020 15:15:07
User entered '20 Sep 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:15:07
User opened query 'Date of dosing discontinuation is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	09 Oct 2020 15:14:36
User opened query 'Date of dosing discontinuation is after date of death. Please update as appropriate.' (Site from System).	System	09 Oct 2020 15:11:25
User entered '8 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:10:16

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:06:55

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:57
User entered 'Death (DEATH)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	09 Oct 2020 15:15:14
User entered 'SAE (specify) (SAE)'	Eileen Euperio (b) (4)	09 Oct 2020 15:10:16

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:57
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	09 Oct 2020 15:15:21
User entered empty; reason for change Data Entry Error	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:15:21
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	09 Oct 2020 15:15:14
User entered 'Suspected cardiopulmonary arrest due to MI resulting in death on 20Sep2020, site notified on 08Oct2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:10:16

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:55

Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:12
User closed query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	09 Oct 2020 15:14:36
User entered '20 Sep 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:14:36
User opened query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	09 Oct 2020 15:11:25
User entered '08 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:11:25

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:55

Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:12
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	09 Oct 2020 15:14:48
User entered 'Death (DEATH)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:14:48
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	09 Oct 2020 15:11:25
User entered 'SAE (specify) (SAE)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:11:25

Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:06:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:34
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	28 Jan 2021 22:58:11
User entered empty; reason for change Data Entry Error	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:58:11
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	28 Jan 2021 22:57:58
DataPoint Un-verified.	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:57:58
User entered 'AE #1' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:57:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:12
User entered empty; reason for change Data Entry Error	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:14:48
User entered 'Suspected cardiopulmonary arrest due to acute MI resulting in death on 20Sep2020, site notified on 08Oct2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:11:25

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Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:06:55

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
User closed query 'Per CDM: thank you for updating; however, please add AE record # (i.e AE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:55:04
Query 'Per CDM: thank you for updating; however, please add AE record # (i.e AE#1, etc.)' answered with 'autoquery appears if AE #1 is added in line above as the reason is death and log line only asks for specification if AE, SAE, Physician Decision, withdrawal of consent, PD, or other' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 22:59:49
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:02:13
User opened query 'Per CDM: thank you for updating; however, please add AE record # (i.e AE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:13:43
User closed query 'Per CDM: reason for discontinuation is Death however, main cause of death is recorded as Other. Please consider recorded the AE/SAE record number and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:11:05
Query 'Per CDM: reason for discontinuation is Death however, main cause of death is recorded as Other. Please consider recorded the AE/SAE record number and make all appropriate updates.' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:28:16
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	19 Nov 2020 23:28:12
User opened query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	19 Nov 2020 23:27:54
DataPoint Un-verified.	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:27:54
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:27:54

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:55

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User opened query 'Per CDM: reason for discontinuation is Death however, main cause of death is recorded as Other. Please consider recorded the AE/SAE record number and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:55:50
Query 'Per CDM: please consider selecting 'Adverse Event' and make all applicable updates.' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:54:19
Query 'Per CDM: please consider selecting 'Serious Adverse Event (Specify)' and make all applicable updates. ' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:53:51
User opened query 'Per CDM: please consider selecting 'Serious Adverse Event (Specify)' and make all applicable updates. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:53:50
User opened query 'Per CDM: please consider selecting 'Adverse Event' and make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:41:17
Query 'Per CDM: reason for discontinuation is recorded as Death, per CCGs please recorded AE record number. Update accordingly or clarify' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:39:31
User opened query 'Per CDM: reason for discontinuation is recorded as Death, per CCGs please recorded AE record number. Update accordingly or clarify' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:47:46
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:12
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	09 Oct 2020 15:14:55
User entered 'Other (OTHER)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:14:55
User opened query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	09 Oct 2020 15:11:25
User entered 'Adverse event (ADVERSE EVENT)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:11:25

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:55

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 01:02:20
DataPoint Un-verified.	Eileen Euperio (b) (4)	19 Nov 2020 23:28:12
User entered empty; reason for change Data Entry Error	(b) (4) Eileen Euperio (b) (4)	19 Nov 2020 23:28:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:12
User entered 'Suspected cardiopulmonary arrest due to acute MI resulting in death on 20Sep2020, site notified on 08Oct2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:11:25

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:55

Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:34
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:12
User entered '20 Sep 2020'	Eileen Euperio (b) (4)	09 Oct 2020 15:11:25
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:55

Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:34
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
DataPoint Un-verified.	Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 21:38:40
User entered 'Yes (Y)' reason for change: New Information	Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 21:38:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:12
User entered 'Unknown (UNK)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:11:25

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'USA-US203-2020-MRNA-1273-P301000003'	System	08 Oct 2020 15:54:27

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'Yes (Y)'	System	08 Oct 2020 15:54:27

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'Yes (Y)'	System	08 Oct 2020 15:54:27

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:17
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Un-reviewed for Safety.	System	26 Feb 2021 17:53:55
DataPoint Un-verified.	System	26 Feb 2021 17:53:55
User entered 'Paul'	System	26 Feb 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Paul'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:19
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Un-reviewed for Safety.	System	26 Feb 2021 17:53:55
DataPoint Un-verified.	System	26 Feb 2021 17:53:55
User entered 'Pickrell'	System	26 Feb 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Pickrell'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '4534 West Gate Blvd. suite 110'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Austin'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'TX'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '78745'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41
	(b) (4)	

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:57:19
User entered 'US'	System	08 Oct 2020 15:55:13

Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered '5'	System	26 Feb 2021 17:53:55
User entered '4'	System	02 Feb 2021 15:41:25
User entered '3'	System	29 Jan 2021 20:24:02
User entered '2'	System	28 Oct 2020 13:02:09
User entered '1'	System	08 Oct 2020 15:55:13

Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'USA-US203-2020-MRNA-1273-P301000003'	System	08 Oct 2020 15:54:27

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'Yes (Y)'	System	08 Oct 2020 15:54:27

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'Yes (Y)'	System	08 Oct 2020 15:54:27

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

FDA-CBER-2022-1614-2824581

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

FDA-CBER-2022-1614-2824585

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:17
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Un-reviewed for Safety.	System	26 Feb 2021 17:53:55
DataPoint Un-verified.	System	26 Feb 2021 17:53:55
User entered 'Paul'	System	26 Feb 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Paul'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:19
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Un-reviewed for Safety.	System	26 Feb 2021 17:53:55
DataPoint Un-verified.	System	26 Feb 2021 17:53:55
User entered 'Pickrell'	System	26 Feb 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Pickrell'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '4534 West Gate Blvd. suite 110'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Austin'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'TX'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41
	(b) (4)	

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '78745'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41
	(b) (4)	

FDA-CBER-2022-1614-2824591

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:57:19
User entered 'US'	System	08 Oct 2020 15:55:13

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered '5'	System	26 Feb 2021 17:53:55
User entered '4'	System	02 Feb 2021 15:41:25
User entered '3'	System	29 Jan 2021 20:24:02
User entered '2'	System	28 Oct 2020 13:02:09
User entered '1'	System	08 Oct 2020 15:55:13

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '08/Oct/2020 15:55'	System	08 Oct 2020 15:55:13

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '1'	(b) (4), (b) (6)	08 Oct 2020 15:55:13

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55

SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'USA-US203-2020-MRNA-1273-P301000003'	System	08 Oct 2020 15:54:27

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'Yes (Y)'	System	08 Oct 2020 15:54:27

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'Yes (Y)'	System	08 Oct 2020 15:54:27

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

FDA-CBER-2022-1614-2824600

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

FDA-CBER-2022-1614-2824603

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:17
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Un-reviewed for Safety.	System	26 Feb 2021 17:53:55
DataPoint Un-verified.	System	26 Feb 2021 17:53:55
User entered 'Paul'	System	26 Feb 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Paul'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:19
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Un-reviewed for Safety.	System	26 Feb 2021 17:53:55
DataPoint Un-verified.	System	26 Feb 2021 17:53:55
User entered 'Pickrell'	System	26 Feb 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Pickrell'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '4534 West Gate Blvd. suite 110'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Austin'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'TX'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '78745'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41
	(b) (4)	

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:57:19
User entered 'US'	System	08 Oct 2020 15:55:13

FDA-CBER-2022-1614-2824610

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered '5'	System	26 Feb 2021 17:53:55
User entered '4'	System	02 Feb 2021 15:41:25
User entered '3'	System	29 Jan 2021 20:24:02
User entered '2'	System	28 Oct 2020 13:02:09
User entered '1'	System	08 Oct 2020 15:55:13

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:21:16
User entered '28/Oct/2020 09:02'	System	28 Oct 2020 13:02:09

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 13:02:09

SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'USA-US203-2020-MRNA-1273-P301000003'	System	08 Oct 2020 15:54:27

FDA-CBER-2022-1614-2824614

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'Yes (Y)'	System	08 Oct 2020 15:54:27

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'Yes (Y)'	System	08 Oct 2020 15:54:27

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

FDA-CBER-2022-1614-2824617

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:17
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Un-reviewed for Safety.	System	26 Feb 2021 17:53:55
DataPoint Un-verified.	System	26 Feb 2021 17:53:55
User entered 'Paul'	System	26 Feb 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Paul'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:19
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Un-reviewed for Safety.	System	26 Feb 2021 17:53:55
DataPoint Un-verified.	System	26 Feb 2021 17:53:55
User entered 'Pickrell'	System	26 Feb 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Pickrell'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '4534 West Gate Blvd. suite 110'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41

Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Austin'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'TX'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '78745'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:57:19
User entered 'US'	System	08 Oct 2020 15:55:13

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered '5'	System	26 Feb 2021 17:53:55
User entered '4'	System	02 Feb 2021 15:41:25
User entered '3'	System	29 Jan 2021 20:24:02
User entered '2'	System	28 Oct 2020 13:02:09
User entered '1'	System	08 Oct 2020 15:55:13

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:40
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '29/Jan/2021 15:23'	System	29 Jan 2021 20:24:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:41:11
User entered '1'	(b) (4), (b) (6)	29 Jan 2021 20:24:02

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'USA-US203-2020-MRNA-1273-P301000003'	System	08 Oct 2020 15:54:27

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'Yes (Y)'	System	08 Oct 2020 15:54:27

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'Yes (Y)'	System	08 Oct 2020 15:54:27

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:17
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Un-reviewed for Safety.	System	26 Feb 2021 17:53:55
DataPoint Un-verified.	System	26 Feb 2021 17:53:55
User entered 'Paul'	System	26 Feb 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Paul'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

FDA-CBER-2022-1614-2824640

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:19
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Un-reviewed for Safety.	System	26 Feb 2021 17:53:55
DataPoint Un-verified.	System	26 Feb 2021 17:53:55
User entered 'Pickrell'	System	26 Feb 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Pickrell'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '4534 West Gate Blvd. suite 110'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41
	(b) (4)	

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Austin'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'TX'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '78745'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:57:19
User entered 'US'	System	08 Oct 2020 15:55:13

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered '5'	System	26 Feb 2021 17:53:55
User entered '4'	System	02 Feb 2021 15:41:25
User entered '3'	System	29 Jan 2021 20:24:02
User entered '2'	System	28 Oct 2020 13:02:09
User entered '1'	System	08 Oct 2020 15:55:13

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:06:55

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:40
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '02/Feb/2021 10:41'	System	02 Feb 2021 15:41:25

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:40
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:53:37
User entered '1'	(b) (4), (b) (6)	02 Feb 2021 15:41:25

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'USA-US203-2020-MRNA-1273-P301000003'	System	08 Oct 2020 15:54:27

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'Yes (Y)'	System	08 Oct 2020 15:54:27

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'Yes (Y)'	System	08 Oct 2020 15:54:27

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:54:50
User entered 'No (N)'	System	08 Oct 2020 15:54:27

FDA-CBER-2022-1614-2824657

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:17
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Un-reviewed for Safety.	System	26 Feb 2021 17:53:55
DataPoint Un-verified.	System	26 Feb 2021 17:53:55
User entered 'Paul'	System	26 Feb 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Paul'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:19
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
Un-reviewed for Safety.	System	26 Feb 2021 17:53:55
DataPoint Un-verified.	System	26 Feb 2021 17:53:55
User entered 'Pickrell'	System	26 Feb 2021 17:53:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Pickrell'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

FDA-CBER-2022-1614-2824659

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '4534 West Gate Blvd. suite 110'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'Austin'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered 'TX'	Eileen Euperio (b) (4)	08 Oct 2020 16:28:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
Un-reviewed for Safety.	System	28 Oct 2020 13:02:09
DataPoint Un-verified.	System	28 Oct 2020 13:02:09
User entered empty.	System	28 Oct 2020 13:02:09
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:44
User entered '78745'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:28:41

US3342256

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:55

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:57:19
User entered 'US'	System	08 Oct 2020 15:55:13

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 17:06:55
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
User entered '5'	System	26 Feb 2021 17:53:55
User entered '4'	System	02 Feb 2021 15:41:25
User entered '3'	System	29 Jan 2021 20:24:02
User entered '2'	System	28 Oct 2020 13:02:09
User entered '1'	System	08 Oct 2020 15:55:13

US3342256
Folder: SAE USA-US203-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 17:06:55
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:40
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:18:27
User entered '26/Feb/2021 11:53'	System	26 Feb 2021 17:53:55

Folder: SAE USA-US203-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 21:05:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:18:27
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:53:55