

US3342256 (Prod: Tekton Research- Austin)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:01:39

All time stamps listed in this document are displayed in GMT

US3342256

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:39

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

Date of Birth (MMM yyyy)	(b) (6) 1977
Age	43
Age Units	YEARS
Age (Derived)	43
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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

Generated On: 26 Nov 2020 11:01:39

Date of Informed Consent (<i>dd MMM yyyy</i>)	14 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:39

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:39

Condition	DIVERTICULOSIS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:39

Condition	GASTRIC SLEEVE SURGERY
Start date (dd MMM yyyy)	UN MAY 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN 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)

Generated On: 26 Nov 2020 11:01:39

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:39

Condition	TOOTH EXTRACTION
Start date (dd MMM yyyy)	UN JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN 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)

Generated On: 26 Nov 2020 11:01:39

Condition	TOOTH INFECTION
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN 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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:37 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 08:37
Height (<i>xxx.x</i>)	188.5 cm
Weight (<i>xxx.x</i>)	102.9 kg
BMI (<i>xxx.x</i>)	28.95961 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:39

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.

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:39

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

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

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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

Generated On: 26 Nov 2020 11:01:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:39

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

Generated On: 26 Nov 2020 11:01:39

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	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)

Generated On: 26 Nov 2020 11:01:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	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

Generated On: 26 Nov 2020 11:01:39

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:39

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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 <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
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

Generated On: 26 Nov 2020 11:01:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	14 SEP 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 11:01:39

Collection date (<i>dd MMM yyyy</i>)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 11:01:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:39

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:39

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

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:39

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

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:39

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

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:39

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:39

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:39

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: 26 Nov 2020 11:01:39

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: 26 Nov 2020 11:01:39

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

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:39

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 11:01:39

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 11:01:39

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:39

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:39

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 11:01:39

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: 26 Nov 2020 11:01:39

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: 26 Nov 2020 11:01:39

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 ☐

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:39

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

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:39

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 ☒

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:39

Yes <input type="checkbox"/>	
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: 26 Nov 2020 11:01:39

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 ☒

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:39

Yes <input type="checkbox"/>	
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: 26 Nov 2020 11:01:39

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 ☒

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:39

Yes <input type="checkbox"/>	
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: 26 Nov 2020 11:01:39

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 ☒

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:39

Yes <input type="checkbox"/>	
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: 26 Nov 2020 11:01:39

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 ☒

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:39

Yes <input type="checkbox"/>	
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

Generated On: 26 Nov 2020 11:01:39

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

If Contact Not Made, please provide Comments

LEFT A VOICEMAIL ONCE
EACH DAY FROM 21SEP2020 TO
24SEP2020. ALSO SENT AN
EMAIL ON 23SEP2020.

US3342256

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342256

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:39

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

If Contact Not Made, please provide Comments

LEFT A VOICEMAIL ONCE
EACH DAY FROM 29SEP2020 -
01OCT2020. ALSO SENT A TEXT
REMINDER ON 01OCT2020.

US3342256

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342256

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:39

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

Generated On: 26 Nov 2020 11:01:39

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3342256

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:01:39

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3342256

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:01:39

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3342256

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:39

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)

Generated On: 26 Nov 2020 11:01:39

AEID	USA-US203-2020-MRNA-1273-P30 1000003
Adverse event	CARDIOPULMONARY ARREST
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	63 of 602

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

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

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

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

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

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:39

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

Yes ☒

No ☐

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

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:39

Name of Medication	ADVIL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HEADACHES
Dose per administration	400
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:39

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<input type="text"/>	
Interval Dosage Unit Number (derived)	<input type="text"/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342256

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:01:39

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3342256

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:01:39

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 _____

US3342256

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:39

Date of study discontinuation/completion (dd MMM yyyy) 20 SEP 2020

Reason for discontinuation

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

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

If reason for discontinuation is Death, main cause of death

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

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 20 SEP 2020

Was autopsy performed?

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

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

SAEID	USA-US203-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3342256

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:01:39

SAEID	USA-US203-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
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

US3342256

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

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:01:39

SAEID	USA-US203-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
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

Audit

US3342256 (Prod: Tekton Research- Austin)

US3342256

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:39

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3342256'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	14 Sep 2020 13:45:18

US3342256

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:01
User entered '14 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 13:45:20

US3342256

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:01
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:40:23

US3342256

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	14 Sep 2020 14:40:23

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1977'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Sep 2020 13:45:22

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

[Age](#)

Audit	User	Time (GMT)
User entered '43'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '43'	System	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

White

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

Unknown

Audit	User	Time (GMT)
User entered 'I'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:39

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:05

US3342256

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:39

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:39

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:39

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:20

US3342256

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Sep 2020 13:45:20

US3342256

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 14:41:25

US3342256

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:39

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:25

US3342256

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:41:38

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:39

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:39

Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:39

Start Year (derived)

Audit	User	Time (GMT)
User entered '2010'	System	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 14:42:20

US3342256

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:39

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered 'May 2014'	System	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered '2014'	System	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered 'May 2014'	System	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered '2014'	System	14 Sep 2020 14:42:49

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:39

Condition

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered '2007'	System	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 14:43:05

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:39

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Sep 2020 14:43:30

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:39

Condition

Audit	User	Time (GMT)
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)	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)	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)	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Sep 2020 14:43:53

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered '08:37'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 08:37'	System	14 Sep 2020 14:45:12

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

Height (xxx.x)

Audit	User	Time (GMT)
User entered '188.5' cm	Morgan Schulle (b) (4)	14 Sep 2020 14:45:12
DataPoint set to visible.	(b) (4) System	14 Sep 2020 14:41:25

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '102.9' kg	Morgan Schulle (b) (4)	14 Sep 2020 14:45:12
DataPoint set to visible.	(b) (4) System	14 Sep 2020 14:41:25

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:12

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 14:45:12

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 14:45:12

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 14:45:12

US3342256

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 14:45:12

US3342256

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:39

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:21

US3342256

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Other

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:39

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:39

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:39

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:39

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:39

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered 'I'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:39

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:45:52

US3342256

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:39

[Specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	14 Sep 2020 14:46:19

US3342256

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:14:39
User entered '14 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 14:15:14

US3342256

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:39

What was the participant's randomization number?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:14:39
User entered '113647'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 14:15:14

US3342256

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(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)	14 Sep 2020 14:15:14

US3342256

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Liver Disease](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Height](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Weight](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Height](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Weight](#)

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 11:01:39

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Temperature (xxx.x)

Audit	User	Time (GMT)
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

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:39

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:39

[Height](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Weight](#)

Audit	User	Time (GMT)
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 (2)

Generated On: 26 Nov 2020 11:01:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:00
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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 System data change (Site from 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

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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 System data change (Site from 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)	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:39

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:39

[If Other, specify](#)

Audit	User	Time (GMT)
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 (2)

Generated On: 26 Nov 2020 11:01:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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 System data change (Site from 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

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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 System data change (Site from 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

US3342256

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:01:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 15:26:10
User entered empty.	System	14 Sep 2020 14:47:25

US3342256

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:10
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:31

US3342256

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:39

If No, reason not given

Audit	User	Time (GMT)
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

US3342256

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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

US3342256

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 14:47:39

US3342256

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:25
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:47:39

US3342256

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:25
User entered 'ONCE'	System	14 Sep 2020 14:47:39

US3342256

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 14:47:39

US3342256

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:30
User entered '14 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	14 Sep 2020 14:48:09

US3342256

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	14 Sep 2020 14:48:09

US3342256

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 09:21'	System	14 Sep 2020 15:13:34
User entered empty.	System	14 Sep 2020 14:48:09

US3342256

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3342256

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:39

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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) (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) (b) (4)	14 Sep 2020 14:49:27

US3342256

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4)	14 Sep 2020 14:49:27

US3342256

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3342256

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:15:55
User entered empty.	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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 14:49:27

US3342256

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:49:34

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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' User entered '96.7'	System	14 Sep 2020 15:25:12
	System	14 Sep 2020 15:25:12

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 10:11'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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' User entered '97.3'	System	15 Sep 2020 01:25:50
	System	15 Sep 2020 01:25:50

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 13:36'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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' User entered '97.8'	System	16 Sep 2020 02:50:32

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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' User entered '15 Sep 2020 21:49'	System	16 Sep 2020 02:50:32
	System	16 Sep 2020 02:50:32

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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' User entered '97.3'	System	18 Sep 2020 08:49:19
	System	18 Sep 2020 08:49:19

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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' User entered '18 Sep 2020 03:49'	System	18 Sep 2020 08:49:19
	System	18 Sep 2020 08:49:19

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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' User entered '98.5'	System	19 Sep 2020 01:04:44
	System	19 Sep 2020 01:04:44

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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' User entered '18 Sep 2020 20:04'	System	19 Sep 2020 01:04:44
	System	19 Sep 2020 01:04:44

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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' User entered 'Yes (Y)'	System	20 Sep 2020 05:22:07
	System	20 Sep 2020 05:22:07

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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' User entered '97.6'	System	20 Sep 2020 05:22:07
	System	20 Sep 2020 05:22:07

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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' User entered '20 Sep 2020 00:22'	System	20 Sep 2020 05:22:07
	System	20 Sep 2020 05:22:07

US3342256

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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' User entered 'None (1)'	System	19 Sep 2020 01:04:59
	System	19 Sep 2020 01:04:59

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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' User entered 'None (1)'	System	19 Sep 2020 01:04:59

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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' User entered '18 Sep 2020 20:04'	System	19 Sep 2020 01:04:59
	System	19 Sep 2020 01:04:59

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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

US3342256

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:39

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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' User entered 'None (0)'	System	15 Sep 2020 01:26:35
	System	15 Sep 2020 01:26:35

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

CHILLS

Audit	User	Time (GMT)
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' User entered 'None (0)'	System	15 Sep 2020 01:26:35
	System	15 Sep 2020 01:26:35

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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' User entered 'No (N)'	System	15 Sep 2020 01:26:35

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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' User entered '14 Sep 2020 20:26'	System	15 Sep 2020 01:26:35
	System	15 Sep 2020 01:26:35

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 13:36'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

HEADACHE

Audit	User	Time (GMT)
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' User entered 'None (0)'	System	18 Sep 2020 08:49:56
	System	18 Sep 2020 08:49:56

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:39

FATIGUE

Audit	User	Time (GMT)
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' User entered 'None (0)'	System	18 Sep 2020 08:49:56
	System	18 Sep 2020 08:49:56

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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' User entered 'None (0)'	System	18 Sep 2020 08:49:56
	System	18 Sep 2020 08:49:56

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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' User entered 'None (0)'	System	18 Sep 2020 08:49:56
	System	18 Sep 2020 08:49:56

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

CHILLS

Audit	User	Time (GMT)
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' User entered 'None (0)'	System	18 Sep 2020 08:49:56
	System	18 Sep 2020 08:49:56

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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' User entered '18 Sep 2020 03:49'	System	18 Sep 2020 08:49:56
	System	18 Sep 2020 08:49:56

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 15:14:42

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:39

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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' User entered 'None (0)'	System	20 Sep 2020 05:22:36
	System	20 Sep 2020 05:22:36

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
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' User entered 'None (0)'	System	20 Sep 2020 05:22:36
	System	20 Sep 2020 05:22:36

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:39

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Time stamp](#)

Audit	User	Time (GMT)
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' User entered '20 Sep 2020 00:22'	System	20 Sep 2020 05:22:36
	System	20 Sep 2020 05:22:36

US3342256

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:16:31
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	25 Sep 2020 13:04:32

US3342256

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(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)	25 Sep 2020 13:04:32

US3342256

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:22:29
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	25 Sep 2020 13:04:38
	(b) (4)	

US3342256

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 13:04:38

US3342256

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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 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
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

US3342256

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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)	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).	(b) (4)	
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 15:14:36
User entered '1 Oct 2020'	System	09 Oct 2020 15:11:25
	Ethan Shotton (b) (4)	01 Oct 2020 22:37:23
	(b) (4)	

US3342256

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(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)	01 Oct 2020 22:37:23

US3342256

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:04:11
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	01 Oct 2020 22:37:26
	(b) (4)	

US3342256

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Oct 2020 22:37:26

US3342256

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3342256

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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
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: 26 Nov 2020 11:01:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:05:56
User entered 'Contact Not Made (CONTACT NOT MADE)'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 16:29:38

US3342256

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:05:46
User entered 'No (N)'	Eileen Euperio (b) (4)	08 Oct 2020 16:29:43
	(b) (4)	

US3342256

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 16:29:43

US3342256

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:56
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:26:49

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[AEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
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

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Adverse event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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
	(b) (4)	

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Ongoing?](#)

Audit	User	Time (GMT)
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)	

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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
	(b) (4)	

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Severity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered '1'	Eileen Euperio (b) (4)	08 Oct 2020 15:31:48
	(b) (4)	

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'Not Applicable (NOT APPLICABLE)'	Eileen Euperio (b) (4)	08 Oct 2020 15:31:48
	(b) (4)	

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[None](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
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
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

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:45
User entered 'Fatal (FATAL)'	Eileen Euperio (b) (4)	08 Oct 2020 15:31:48
	(b) (4)	

US3342256

Folder: Adverse Events

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Generated On: 26 Nov 2020 11:01:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
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)	

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Folder: Adverse Events

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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)

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[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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[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)	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)	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)	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)	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)	10 Nov 2020 22:51:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[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).	(b) (4), (b) (6)	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.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:01:48
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:01:47

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Folder: Adverse Events

Form: Adverse Events (1)

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[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)	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)	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)	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)	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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Oct 2020 15:31:48

US3342256

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Oct 2020 15:31:48

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:39

[Prophylaxis](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:39

[Indication](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:39

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:39

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	19 Nov 2020 23:30:57
DataPoint Un-verified.	(b) (4)	19 Nov 2020 23:30:50
User entered 'UN UNK 2008' reason for change: Data Entry Error	Eileen Euperio (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)	14 Sep 2020 14:50:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:32
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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

US3342256

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 14:50:57

US3342256

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:01:39

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3342256

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:01:39

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:57
User entered 'Death (DEATH)' reason for change:	Eileen Euperio (b) (4)	09 Oct 2020 15:15:14
Data Entry Error	(b) (4)	
User entered 'SAE (specify) (SAE)'	Eileen Euperio (b) (4)	09 Oct 2020 15:10:16
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	09 Oct 2020 15:10:16

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:39

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	09 Oct 2020 15:14:36
User opened query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	(b) (4)	09 Oct 2020 15:11:25
User entered '08 Oct 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: 26 Nov 2020 11:01:39

[Reason for discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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).	(b) (4)	09 Oct 2020 15:11:25
User entered 'SAE (specify) (SAE)'	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: 26 Nov 2020 11:01:39

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

Audit	User	Time (GMT)
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)	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)	09 Oct 2020 15:11:25

US3342256

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:39

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
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
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

US3342256

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:39

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Query 'Per CDM: reason for discontinuation is recorded as Death, per CCGs please record 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 record 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)	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).	(b) (4)	09 Oct 2020 15:11:25
User entered 'Adverse event (ADVERSE EVENT)'	Eileen Euperio (b) (4)	09 Oct 2020 15:11:25

US3342256

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:39

If main cause of death is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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)	09 Oct 2020 15:11:25
	(b) (4)	

US3342256

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:39

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:12
User entered '20 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 15:11:25

US3342256

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:39

[Was autopsy performed?](#)

Audit	User	Time (GMT)
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

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Death

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
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)	08 Oct 2020 16:28:41

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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)	08 Oct 2020 16:28:41

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

Site Address: [Street](#)

Audit	User	Time (GMT)
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

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

Site Address: City

Audit	User	Time (GMT)
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

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

Site Address: [State](#)

Audit	User	Time (GMT)
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

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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

Generated On: 26 Nov 2020 11:01:39

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Death

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
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)	08 Oct 2020 16:28:41

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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)	08 Oct 2020 16:28:41

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

Site Address: [Street](#)

Audit	User	Time (GMT)
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

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

Site Address: City

Audit	User	Time (GMT)
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

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

Site Address: [State](#)

Audit	User	Time (GMT)
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

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 11:01:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
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 'I'	(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: 26 Nov 2020 11:01:39

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

Serious

Audit	User	Time (GMT)
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

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Death

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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

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[Other medically important event](#)

Audit	User	Time (GMT)
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

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[Investigator's First Name](#)

Audit	User	Time (GMT)
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)	08 Oct 2020 16:28:41

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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)	08 Oct 2020 16:28:41

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

Site Address: [Street](#)

Audit	User	Time (GMT)
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

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

Site Address: [City](#)

Audit	User	Time (GMT)
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

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

Site Address: [State](#)

Audit	User	Time (GMT)
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

US3342256

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

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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 (2)

Generated On: 26 Nov 2020 11:01:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:21:16
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 13:02:09