

US3602037 (Prod: Hackensack University Medical Center)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:09:18

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US3602037

Form: Participant Creation

Generated On: 26 Nov 2020 11:09:18

[Participant ID](#)

US3602037

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

US3602037

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:18

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

Date of Birth (MMM yyyy)	(b) (6) 1972
Age	47
Age Units	YEARS
Age (Derived)	47
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☒
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	True
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:18

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 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:09:18

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:09:18

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:18

Condition	SEASONAL ALLERGIE--> PRESSURE HAS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:18

Condition	VASOVAGAL RESPONSE WITH BLOOD WORK
Start date (dd MMM yyyy)	14 SEP 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	14 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:50 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 13:50
Height (<i>xxx.x</i>)	66 in
Weight (<i>xxx.x</i>)	185 lb
BMI (<i>xxx.x</i>)	29.92222 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:18

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 11:09:18

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

Generated On: 26 Nov 2020 11:09:18

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 11:09:18

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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:18

What was the date of randomization? (dd MMM yyyy) 14 SEP 2020

What was the participant's randomization number? 113927

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 11:09:18

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 11:09:18

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 13:50
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 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 11:09:18

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☐ No ☒
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:18

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: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:18

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:18

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

14 SEP 2020

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

15:00 (24 HR)

Collection date and time (derived)

14 SEP 2020 15:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:18

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:18

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

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Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:18

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

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:09:18

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:09:18

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

AEID	USA-US079-2020-MRNA-1273-P30 1000002
Adverse event	VASOVAGAL EPISODE WHILE GETTING BLOOD DRAWN
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	14 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

SUBJECT FAINTED WHILE
HAVING BLOOD DRAWN.
(b) (6), CRC PRESENT
AT THE TIME. RRT CALLED AT
2:45PM. SUBJECT REFUSED TO
GO TO ER, AS PER RRT. VITALS
PERFORMED AND STABLE.
OFFERED JUICE AND WATER.
SUBJECT STATES TO FEELING
OKAY.

ATTEMPTED BLOOD DRAW X2
BY (b) (6), APN. AT THIS
TIME SUBJECT STILL WANTS
TO CONTINUE WITH THE
STUDY. ADVISED TO CALL US
TO RESCHEDULE FOR DAY 1
(VACCINATION DAY).

CONTACTED SUBJECT
REGARDING SCHEDULING FOR
STUDY INJECTION DOSE 1. DUE
TO PREVIOUS EXPERIENCE
WITH BLOOD WORK
(VASOVAGAL RESPONSE),
SUBJECT DECIDED TO NOT
CONTINUE WITH THE STUDY.
CONFIRMED WITH THE
SUBJECT THAT HE WILL BE
WITHDRAWN FROM FURTHER
STUDY ACTIVITIES. DR.
BALANI NOTIFIED AND
AGREED. SUBJECT
TREATMENT
DISCONTINUATION ENTERED
IN IVRX ON 25 SEPT 2020 AT
4:06 PM.

Serious Adverse Event Derived (CSA Programming Field Only)	0

Medically Attended AE Derived (CSA Programming Field Only)	0

Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:09:18

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

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

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3602037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:09:18

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:18

Date of dosing discontinuation (dd MMM yyyy)

25 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

A.E LOG LINE #1

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:18

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

Reason for discontinuation

AE (specify) ☒

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by participant (specify) ☐

Other ☐

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

AE LOG LINE 1

AEID:

USA-US079-2020-MRNA-1273-P30

1000002

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

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Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

SAEID	USA-US079-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

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Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:18

SAEID	USA-US079-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	14/OCT/2020 08:19
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

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Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:09:18

SAEID	USA-US079-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/OCT/2020 17:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

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Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:09:18

SAEID	USA-US079-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/NOV/2020 14:27
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

US3602037 (Prod: Hackensack University Medical Center)

US3602037

Form: Participant Creation

Generated On: 26 Nov 2020 11:09:18

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3602037'	RWS_ENDPOINT ENDPOINT (b) (4) 	14 Sep 2020 17:44:56

US3602037

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 19:47:22

US3602037

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '14 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	14 Sep 2020 17:44:57

US3602037

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Sep 2020 19:47:22

US3602037

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:18

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	14 Sep 2020 19:47:22

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered (b) (6) 1972'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Sep 2020 17:44:58

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

[Age](#)

Audit	User	Time (GMT)
User entered '47'	(b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '47'	System	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

White

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

Unknown

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:18

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:18

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:18

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:18

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:18

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Sep 2020 17:44:57

US3602037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 19:57:25

US3602037

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 19:57:25

US3602037

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:09:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:33:00
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 20:06:44

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 13:58:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 13:58:39
Data point term sent to Coder	System	28 Oct 2020 16:33:59
User entered 'Seasonal allergie--> pressure HAs'	(b) (4), (b) (6) (b) (4)	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Vasovagal reaction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 08:46:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 08:46:43
Data point term sent to Coder	System	28 Oct 2020 16:35:02
User entered 'Vasovagal response with blood work'	(b) (4), (b) (6)	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '2020'	System	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '13:50'	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 13:50'	System	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '66' in	(b) (4), (b) (6)	14 Sep 2020 20:09:50
DataPoint set to visible.	System	14 Sep 2020 19:57:25

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '185' lb	(b) (4), (b) (6)	14 Sep 2020 20:09:50
DataPoint set to visible.	System	14 Sep 2020 19:57:25

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '29.92222'	System	14 Sep 2020 20:09:50
DataPoint set to visible.	System	14 Sep 2020 19:57:25

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	14 Sep 2020 20:09:50
DataPoint set to visible.	System	14 Sep 2020 19:57:25

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '84'	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '13'	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132'	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '92'	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 20:10:01

US3602037

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 20:10:01

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:05:49
Query 'Data is required. Please complete.' answered with 'SUBJECT WITHDREW, NO INFO IN EMR/EHR' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 20:23:46
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:13:03
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:05:51
Query 'Data is required. Please complete.' answered with 'SUBJECT WITHDREW, NO INFO IN EMR/EHR' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 20:23:50
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:13:03
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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 closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:05:53
Query 'Data is required. Please complete.' answered with 'SUBJECT WITHDREW, NO INFO IN EMR/EHR' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 20:23:52
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:13:03
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:05:55
Query 'Data is required. Please complete.' answered with 'SUBJECT WITHDREW, NO INFO IN EMR/EHR' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 20:23:55
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:13:03
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:05:58
Query 'Data is required. Please complete.' answered with 'SUBJECT WITHDREW, NO INFO IN EMR/EHR' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 20:23:58
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:13:03
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:06:00
Query 'Data is required. Please complete.' answered with 'SUBJECT WITHDREW, NO INFO IN EMR/EHR' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 20:24:01
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:13:03
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:06:02
Query 'Data is required. Please complete.' answered with 'SUBJECT WITHDREW, NO INFO IN EMR/EHR' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 20:24:05
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:13:03
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:06:04
Query 'Data is required. Please complete.' answered with 'SUBJECT WITHDREW, NO INFO IN EMR/EHR' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 20:24:08
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:13:03
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:06:07
Query 'Data is required. Please complete.' answered with 'SUBJECT WITHDREW, NO INFO IN EMR/EHR' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 20:24:11
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:13:03
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:06:09
Query 'Data is required. Please complete.' answered with 'SUBJECT WITHDREW, NO INFO IN EMR/EHR' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 20:24:14
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:13:03
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:06:11
Query 'Data is required. Please complete.' answered with 'SUBJECT WITHDREW, NO INFO IN EMR/EHR' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 20:24:17
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:13:03
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

Other

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:06:13
Query 'Data is required. Please complete.' answered with 'SUBJECT WITHDREW, NO INFO IN EMR/EHR' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 20:24:20
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:13:03
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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'	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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'	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:18

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:14:53

US3602037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 15:14:53

US3602037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Oct 2020 15:14:53

US3602037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:18

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	13 Oct 2020 15:14:53

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '14 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	14 Sep 2020 18:39:59

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:18

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '113927'	RWS_ENDPOINT ENDPOINT (b) (4) 	14 Sep 2020 18:39:59

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) 	14 Sep 2020 18:39:59

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:15:12

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:15:12

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:15:12

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:15:12

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:18

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:15:12

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:15:12
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:11:15
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:11:14

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:18

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:18

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:18

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:18

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '13:50'	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 13:50'	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '84'	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '13'	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132'	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '92'	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:18

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:18

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:16:30

US3602037

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 15:16:30

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:18

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Withdrawal of Consent by Participant (WITHDRAWAL OF CONSENT)'	(b) (4), (b) (6)	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:18

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:56:32

US3602037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 15:56:32

US3602037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:00'	(b) (4), (b) (6)	13 Oct 2020 15:56:32

US3602037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 15:00'	System	13 Oct 2020 15:56:32

US3602037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:23:14

US3602037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:18

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Oct 2020 15:23:14

US3602037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:23:14

US3602037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:23:14

US3602037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:23:14

US3602037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:18

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Oct 2020 15:23:14

US3602037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:23:14

US3602037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:23:14

US3602037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:23:14

US3602037

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:17:56

US3602037

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:17:56

US3602037

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:18:02

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:24:34
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:24:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:20
User entered 'USA-US079-2020-mRNA-1273-P301000002'	System	14 Oct 2020 12:19:16
User entered 'New'	(b) (4), (b) (6)	14 Oct 2020 12:19:16

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Vasovagal attack - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 00:21:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 00:21:24
Data point term sent to Coder	System	13 Oct 2020 15:21:29
User entered 'Vasovagal Episode while getting blood drawn'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered '14 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Oct 2020 15:21:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 15:21:43
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Oct 2020 15:21:17
User entered '14:45'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:21:43
User entered '14 Sep 2020 14:45'	System	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered '14 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	13 Oct 2020 15:21:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 15:21:43
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	13 Oct 2020 15:21:17
User entered '16:00'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:21:43
User entered '14 Sep 2020 16:00'	System	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:31:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	17 Nov 2020 16:31:18
reason for change: New Information		
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).	System	12 Nov 2020 14:26:56
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	12 Nov 2020 14:26:36
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 14:26:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 14:26:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 14:26:56
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 14:26:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:31:18
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	17 Nov 2020 16:31:18
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:31:18
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	17 Nov 2020 16:31:18
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Un-verified.	System	17 Nov 2020 16:31:40
	(b) (4), (b) (6)	17 Nov 2020 16:31:40
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:31:40
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Verified.	System	17 Nov 2020 16:31:18
	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:40:01
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'No Con Procedure' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:31:58
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:31:18
User entered '0' reason for change: New Information	(b) (4), (b) (6)	17 Nov 2020 16:31:18
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:14:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 21:36:25
User closed query 'PV Query: Please confirm that subject were in screening phase at the time of the event.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 21:36:04
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 21:35:34
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'Will add this vasovagal response to medical history' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:32:14
Query 'PV Query: Please confirm that subject were in screening phase at the time of the event.' answered with 'Subject was in the screening and visit 1 day 1 phrase (same day) phrase at the time of event' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:27:25

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[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 'No Medical intervention and/or surgical treatments. Subject refused to go to the ER. "SUBJECT FAINTED WHILE HAVING BLOOD DRAWN. (b) (6) (b) (6), CRC PRESENT AT THE TIME. RRT CALLED AT 2:45PM. SUBJECT REFUSED TO GO TO ER, AS PER RRT. VITALS PERFORMED AND STABLE. OFFERED JUICE AND WATER. SUBJECT STATES TO FEELING OKAY. " as indicated in narrative.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:26:36
User opened query 'PV Query: Please confirm that subject were in screening phase at the time of the event.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:27:36
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 17:27:15
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)	21 Oct 2020 17:26:55

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject fainted while having blood drawn. (b) (6), CRC present at the time. RRT called at 2:45PM. Subject refused to go to ER, as per RRT. Vitals performed and stable. Offered juice and water. Subject states to feeling okay. Attempted blood draw x2 by (b) (6), APN. At this time subject still wants to continue with the study. Advised to call us to reschedule for Day 1 (vaccination day). Contacted subject regarding scheduling for study injection dose 1. Due to previous experience with blood work (vasovagal response), subject decided to not continue with the study. Confirmed with the subject that he will be withdrawn from further study activities. Dr. Balani notified and agreed. Subject treatment discontinuation entered in IVRX on 25 Sept 2020 at 4:06 PM.'	(b) (4), (b) (6)	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 14:26:36
User entered '1'	System	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 15:21:17

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 22:46:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:59:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:08:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:08:59
Data point term sent to Coder	System	24 Nov 2020 18:08:04
Coding entries removed.	(b) (4), (b) (6)	24 Nov 2020 18:07:55
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:34:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:34:16
Data point term sent to Coder	System	13 Oct 2020 16:02:43
User entered 'Claritin'	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.	(b) (4), (b) (6)	24 Nov 2020 18:08:24
' answered with 'Updated entry. Seasonal allergies is already added in Medical History' (Site from DM).		
User entered 'SEASONAL ALLERGIES' reason for change: New Information	(b) (4), (b) (6)	24 Nov 2020 18:07:55
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.	(b) (4), (b) (6)	24 Nov 2020 11:35:22
' (Site from DM).		
User entered 'Seasonal Allergies/ Congestion'	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'unknown'	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'unknown'	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:02:20

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:04:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:04:19
Data point term sent to Coder	System	13 Oct 2020 16:03:44
User entered 'Diphenhydramine'	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with AE or Med History eCRF so there is an appropriate condition recorded. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:36:09
User entered 'Sleep Aid'	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:09:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 16:03:37

US3602037

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:18

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Per CDM : Date of dose discontinuation does not match any dose dates. Please provide clarification .Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:28:59
Query 'Per CDM : Date of dose discontinuation does not match any dose dates. Please provide clarification .Thank you.' answered with 'Subject did not receive 2nd dose of IP' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:23:00
User opened query 'Per CDM : Date of dose discontinuation does not match any dose dates. Please provide clarification .Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:25:25
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 15:22:22

US3602037

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:18

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	13 Oct 2020 15:22:22

US3602037

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Requery: Kindly remove all details and only provide the AE log line#. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:56:01
Query 'Per CDM: Requery: Kindly remove all details and only provide the AE log line#. Thank you.' answered with 'Updated ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:11:56
User entered 'A.E Log line #1' reason for change: Per Query Resolution	(b) (4), (b) (6)	20 Nov 2020 18:11:48
User opened query 'Per CDM: Requery: Kindly remove all details and only provide the AE log line#. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:23:24
User closed query 'Per CDM re-query: Response noted. Kindly consider to update AE record number on eCRF field ("specify"). ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:20:47
Query 'Per CDM re-query: Response noted. Kindly consider to update AE record number on eCRF field ("specify"). ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 13:52:48
User entered 'VASOVAGAL EPISODE WHILE GETTING BLOOD DRAWN OM 09/14/2020----USA-US079-2020-MRNA-1273-P301000002' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Nov 2020 13:52:38
User opened query 'Per CDM re-query: Response noted. Kindly consider to update AE record number on eCRF field ("specify"). ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:22:21
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:22:21
Query 'Per CDM: Please record AE record number instead of details ' answered with 'A.E Record # - I believe is: USA-US079-2020-MRNA-1273-P301000002' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 18:46:39
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:20:52
User entered 'Vasovagal episode while getting blood drawn om 09/14/2020'	(b) (4), (b) (6)	13 Oct 2020 15:22:22

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:18

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm the date of study discontinuation/completion as it does not match the AE date/withdrew consent date. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:31:38
Query 'Per CDM: Please confirm the date of study discontinuation/completion as it does not match the AE date/withdrew consent date. Thank you.'	(b) (4), (b) (6)	18 Nov 2020 16:07:13
answered with 'SUBJECT TREATMENT DISCONTINUATION ENTERED IN IVRX ON 25 SEPT 2020 AT 4:06 PM.' (Site from DM).		
User opened query 'Per CDM: Please confirm the date of study discontinuation/completion as it does not match the AE date/withdrew consent date. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:46:06
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 15:22:56

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:18

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	13 Oct 2020 15:22:56

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User closed query 'Per CCG's if reason for discontinuation is AE sites are to add AE log line number to this field. No other information other than applicable AE log line is to be entered. Please verify if this should be "1" with other information removed per CCGs and AE page.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 01:12:19
Query 'Per CCG's if reason for discontinuation is AE sites are to add AE log line number to this field. No other information other than applicable AE log line is to be entered. Please verify if this should be "1" with other information removed per CCGs and AE page.'	(b) (4), (b) (6)	10 Nov 2020 21:42:20
answered with 'Updated' (Site from CRA).		
User entered 'AE Log Line 1 AEID: USA-US079-2020-MRNA-1273-P301000002 reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Nov 2020 21:42:12
User opened query 'Per CCG's if reason for discontinuation is AE sites are to add AE log line number to this field. No other information other than applicable AE log line is to be entered. Please verify if this should be "1" with other information removed per CCGs and AE page.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 22:36:27
User entered 'Vasovagal episode while getting blood drawn on 09/14/2020'	(b) (4), (b) (6)	13 Oct 2020 15:22:56

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:18

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:22:56

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:18

If main cause of death is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:22:56

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:18

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:22:56

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:18

[Was autopsy performed?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:22:56

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'USA-US079-2020-MRNA-1273-P301000002'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:27:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:35:50
User closed query 'Per source notes entered 05-Nov-2020, this event does not meet the criteria of an SAE. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:35:38
Query 'Per source notes entered 05-Nov-2020, this event does not meet the criteria of an SAE. Please confirm data and update accordingly.' answered with 'event is not an SAE, AE log reflects this. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:53:08
Un-reviewed for Safety.	System	12 Nov 2020 14:26:56
DataPoint Un-verified.	System	12 Nov 2020 14:26:56
User entered 'No (N)'	System	12 Nov 2020 14:26:56
User opened query 'Per source notes entered 05-Nov-2020, this event does not meet the criteria of an SAE. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:15:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Yes (Y)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:56
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:27:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:37:11
Un-reviewed for Safety.	System	12 Nov 2020 14:26:56
DataPoint Un-verified.	System	12 Nov 2020 14:26:56
User entered 'No (N)'	System	12 Nov 2020 14:26:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Yes (Y)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:02
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:03
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Bindu'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:06
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Balani'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:10
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'NJ'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:13
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 21:38:55
User entered 'US'	System	14 Oct 2020 12:19:37

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '3'	System	13 Nov 2020 14:27:49
User entered '2'	System	29 Oct 2020 21:39:11
User entered '1'	System	14 Oct 2020 12:19:37

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'USA-US079-2020-MRNA-1273-P301000002'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:27:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:35:50
User closed query 'Per source notes entered 05-Nov-2020, this event does not meet the criteria of an SAE. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:35:38
Query 'Per source notes entered 05-Nov-2020, this event does not meet the criteria of an SAE. Please confirm data and update accordingly.' answered with 'event is not an SAE, AE log reflects this. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:53:08
Un-reviewed for Safety.	System	12 Nov 2020 14:26:56
DataPoint Un-verified.	System	12 Nov 2020 14:26:56
User entered 'No (N)'	System	12 Nov 2020 14:26:56
User opened query 'Per source notes entered 05-Nov-2020, this event does not meet the criteria of an SAE. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:15:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Yes (Y)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:56
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:27:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:37:11
Un-reviewed for Safety.	System	12 Nov 2020 14:26:56
DataPoint Un-verified.	System	12 Nov 2020 14:26:56
User entered 'No (N)'	System	12 Nov 2020 14:26:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Yes (Y)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:02
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:03
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Bindu'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:06
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Balani'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:10
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'NJ'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:13
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 21:38:55
User entered 'US'	System	14 Oct 2020 12:19:37

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '3'	System	13 Nov 2020 14:27:49
User entered '2'	System	29 Oct 2020 21:39:11
User entered '1'	System	14 Oct 2020 12:19:37

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '14/Oct/2020 08:19'	System	14 Oct 2020 12:19:37

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:18

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)	29 Oct 2020 21:38:55
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 12:19:37

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'USA-US079-2020-MRNA-1273-P301000002'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:27:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:35:50
User closed query 'Per source notes entered 05-Nov-2020, this event does not meet the criteria of an SAE. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:35:38
Query 'Per source notes entered 05-Nov-2020, this event does not meet the criteria of an SAE. Please confirm data and update accordingly.' answered with 'event is not an SAE, AE log reflects this. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:53:08
Un-reviewed for Safety.	System	12 Nov 2020 14:26:56
DataPoint Un-verified.	System	12 Nov 2020 14:26:56
User entered 'No (N)'	System	12 Nov 2020 14:26:56
User opened query 'Per source notes entered 05-Nov-2020, this event does not meet the criteria of an SAE. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:15:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Yes (Y)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:56
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:27:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:37:11
Un-reviewed for Safety.	System	12 Nov 2020 14:26:56
DataPoint Un-verified.	System	12 Nov 2020 14:26:56
User entered 'No (N)'	System	12 Nov 2020 14:26:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Yes (Y)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:02
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:03
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Bindu'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:06
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Balani'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:10
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'NJ'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:13
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 21:38:55
User entered 'US'	System	14 Oct 2020 12:19:37

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '3'	System	13 Nov 2020 14:27:49
User entered '2'	System	29 Oct 2020 21:39:11
User entered '1'	System	14 Oct 2020 12:19:37

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '29/Oct/2020 17:39'	System	29 Oct 2020 21:39:11

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:09:18

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)	13 Nov 2020 14:27:33
User entered '1'	(b) (4), (b) (6)	29 Oct 2020 21:39:11

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'USA-US079-2020-MRNA-1273-P301000002'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:27:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:35:50
User closed query 'Per source notes entered 05-Nov-2020, this event does not meet the criteria of an SAE. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:35:38
Query 'Per source notes entered 05-Nov-2020, this event does not meet the criteria of an SAE. Please confirm data and update accordingly.' answered with 'event is not an SAE, AE log reflects this. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:53:08
Un-reviewed for Safety.	System	12 Nov 2020 14:26:56
DataPoint Un-verified.	System	12 Nov 2020 14:26:56
User entered 'No (N)'	System	12 Nov 2020 14:26:56
User opened query 'Per source notes entered 05-Nov-2020, this event does not meet the criteria of an SAE. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:15:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:49
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Yes (Y)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:52:56
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:27:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:37:11
Un-reviewed for Safety.	System	12 Nov 2020 14:26:56
DataPoint Un-verified.	System	12 Nov 2020 14:26:56
User entered 'No (N)'	System	12 Nov 2020 14:26:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Yes (Y)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:02
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:03
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'No (N)'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Bindu'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:06
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'Balani'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:10
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:19:32
User entered 'NJ'	System	14 Oct 2020 12:19:16

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:53:13
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 21:38:55
User entered 'US'	System	14 Oct 2020 12:19:37

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '3'	System	13 Nov 2020 14:27:49
User entered '2'	System	29 Oct 2020 21:39:11
User entered '1'	System	14 Oct 2020 12:19:37

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '13/Nov/2020 14:27'	System	13 Nov 2020 14:27:49

US3602037

Folder: SAE USA-US079-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:09:18

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 14:27:49