

US3602037 (Prod: Hackensack University Medical Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:10:34

All time stamps listed in this document are displayed in GMT

US3602037

Form: Participant Creation

Data signed: (b) (4) 19 Mar 2021 17:47:48

Generated On: 10 Jun 2021 09:10:34

[Participant ID](#)

US3602037

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

US3602037

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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

US3602037

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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

US3602037

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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

US3602037

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Apr 2021 01:50:18

Generated On: 10 Jun 2021 09:10:34

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3602037

Folder: Screening

Form: Inclusion/Exclusion Criteria

Generated On: 10 Jun 2021 09:10:34

Select inclusion criteria not met and/or exclusion criteria met

Criterion Type

Criterion Identifier

US3602037

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

Were any significant conditions reported?

Yes ☒

No ☐

US3602037

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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

US3602037

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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 <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3602037

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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

US3602037

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 23:58:36

Generated On: 10 Jun 2021 09:10:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 13:50
Height (xxx.x)	66 in
Weight (xxx.x)	185 lb
BMI (xxx.x)	29.92222 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602037

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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.

US3602037

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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

US3602037

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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

US3602037

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:47:50

Generated On: 10 Jun 2021 09:10:34

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

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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 ☒

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Mar 2021 17:47:50

Generated On: 10 Jun 2021 09:10:34

Height	ND - Not Done
Weight	ND - Not Done

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 17:47:50

Generated On: 10 Jun 2021 09:10:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 17:47:50

Generated On: 10 Jun 2021 09:10:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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	

US3602037

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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.

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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?

US3602037

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 00:01:53

Generated On: 10 Jun 2021 09:10:34

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 23:39:34

Generated On: 10 Jun 2021 09:10:34

AEID	USA-US079-2020-MRNA-1273-P30 1000002
Adverse event	VASOVAGAL EPISODE WHILE GETTING BLOOD DRAWN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	23 of 370

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 23:39:34

Generated On: 10 Jun 2021 09:10:34

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

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 23:39:34

Generated On: 10 Jun 2021 09:10:34

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)	

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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

Yes ☒

No ☐

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

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Mar 2021 17:47:48

Generated On: 10 Jun 2021 09:10:34

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

27 of 370

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Mar 2021 17:47:48

Generated On: 10 Jun 2021 09:10:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Mar 2021 17:47:48

Generated On: 10 Jun 2021 09:10:34

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

29 of 370

EAB) (1725)

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Mar 2021 17:47:48

Generated On: 10 Jun 2021 09:10:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3602037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3602037

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 09 Apr 2021 01:50:18

Generated On: 10 Jun 2021 09:10:34

Date of dosing discontinuation (dd MMM yyyy)	25 SEP 2020
--	-------------

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

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

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

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 #1

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3602037

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

Form: Safety Report Form

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

SAEID	USA-US079-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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

US3602037

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

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

SAEID	USA-US079-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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

US3602037

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

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

SAEID	USA-US079-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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

US3602037

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

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Mar 2021 17:47:49

Generated On: 10 Jun 2021 09:10:34

SAEID	USA-US079-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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: 10 Jun 2021 09:10:34

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'US3602037'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 17:44:56

US3602037

Form: Participant Creation

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:47:22

US3602037

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '14 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 17:44:57

US3602037

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:47:22

US3602037

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'SCRN'	System	14 Sep 2020 19:47:22

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered (b) (6) 1972'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 17:44:58

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '47'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'YEARS'	System	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered '47'	System	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:34

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:48:09

US3602037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'Sep 2020'	System	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered '2020'	System	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:34

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User closed query 'Enrollment is recorded as Yes; however, met all criteria is recorded as NO. Please review and reconcile.' (Site from System).	System	05 Apr 2021 22:30:53
Comment added 'Subject did meet all IE criteria prior to enrollment and was, therefore, enrolled. It was only after enrollment, during the blood draw that an A.E occurred which led to the subject withdrawing from the study.'	(b) (4), (b) (6)	05 Apr 2021 15:55:39
User opened query 'Enrollment is recorded as Yes; however, met all criteria is recorded as NO. Please review and reconcile.' (Site from System).	System	05 Apr 2021 15:11:26
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:51:15

US3602037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 17:44:57

US3602037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered '1'	System	05 Apr 2021 22:30:53
User entered empty.	System	02 Apr 2021 16:33:47
User entered '1'	System	14 Sep 2020 19:57:25

US3602037

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:48
User closed query 'Did the subject meet all eligibility criteria? is marked "No", but Subject was randomized Please review and provide any needed correction.' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 09:01:45
User closed query 'Did the subject meet all eligibility criteria? is marked "No", but Subject enrolled is YES. Please review and provide any needed correction.' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 09:01:41
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	05 Apr 2021 22:30:53
Query 'Did the subject meet all eligibility criteria? is marked "No", but Subject enrolled is YES. Please review and provide any needed correction.' answered with 'Per RSM Request.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 15:12:10
Query 'Did the subject meet all eligibility criteria? is marked "No", but Subject was randomized Please review and provide any needed correction.' answered with 'Per RSM Request' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 15:12:05
User opened query 'Did the subject meet all eligibility criteria? is marked "No", but Subject enrolled is YES. Please review and provide any needed correction.' (Site from System).	System	05 Apr 2021 15:11:26
User opened query 'Did the subject meet all eligibility criteria? is marked "No", but Subject was randomized Please review and provide any needed correction.' (Site from System).	System	05 Apr 2021 15:11:26
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	05 Apr 2021 15:11:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	04 Apr 2021 05:20:44
Query 'Data is required. Please complete.' answered with 'Data has been removed per the instructions of (b) (6) RSM via email.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 16:47:21
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:33:47

US3602037

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 16:33:47
User entered empty; reason for change New Information	(b) (4), (b) (6)	02 Apr 2021 16:33:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:57:25

US3602037

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:10:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(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: 10 Jun 2021 09:10:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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.	(b) (4) Coder Import (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)	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	28 Oct 2020 16:33:18

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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)	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)	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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'Sep 2020'	System	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered '2020'	System	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	28 Oct 2020 16:34:52

US3602037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 21:41:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 21:41:51
Data point term sent to Coder	System	01 Dec 2020 21:40:53
User entered 'Insomnia'	(b) (4), (b) (6)	01 Dec 2020 21:39:59

US3602037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:39:59

US3602037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:39:59

US3602037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:39:59

US3602037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:39:59

US3602037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:39:59

US3602037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	01 Dec 2020 21:39:59

US3602037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	01 Dec 2020 21:39:59

US3602037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	01 Dec 2020 21:39:59

US3602037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	01 Dec 2020 21:39:59

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '13:50'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered '14 Sep 2020 13:50'	System	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 23:58:36
DataPoint set to visible.	(b) (4)	05 Apr 2021 22:30:53
Signature has been broken.	System	02 Apr 2021 16:33:47
DataPoint set to invisible.	System	02 Apr 2021 16:33:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '66' in	(b) (4)	(b) (4), (b) (6)
DataPoint set to visible.	System	14 Sep 2020 19:57:25

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 23:58:36
DataPoint set to visible.	(b) (4)	05 Apr 2021 22:30:53
Signature has been broken.	System	02 Apr 2021 16:33:47
DataPoint set to invisible.	System	02 Apr 2021 16:33:47
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '185' lb	(b) (4)	(b) (4), (b) (6)
DataPoint set to visible.	System	14 Sep 2020 19:57:25

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint set to visible.	System	05 Apr 2021 22:30:53
DataPoint set to invisible.	System	02 Apr 2021 16:33:47
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: 10 Jun 2021 09:10:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint set to visible.	System	05 Apr 2021 22:30:53
DataPoint set to invisible.	System	02 Apr 2021 16:33:47
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: 10 Jun 2021 09:10:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 03:50:30
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'Updated per query' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:59:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	30 Nov 2020 13:59:20
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:37:02
User entered '98.7' F	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty; reason for change Per Query Resolution	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 13:59:20
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	30 Nov 2020 13:59:20
User entered '84'	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'bpm'	System	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed query 'Per CDM: Response noted. Please Check 'Not done' box. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM: Response noted. Please Check 'Not done' box. Thank you.' answered with "'ND" inserted per query ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 04:18:59
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	01 Dec 2020 15:52:45
User opened query 'Per CDM: Response noted. Please Check 'Not done' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:52:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Dec 2020 15:11:06
Query 'Data is required. Please provide.' answered with 'Screening and Visit Day is the same. Per CCG, "ND" should be selected' (Site from System).	(b) (4), (b) (6)	01 Dec 2020 15:10:41
User opened query 'Data is required. Please provide.' System (Site from System).		30 Nov 2020 14:00:16
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	30 Nov 2020 13:59:20
User entered '13'	(b) (4), (b) (6)	30 Nov 2020 13:59:20
		14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'breaths/min'	System	01 Dec 2020 15:52:27
User entered empty.	System	30 Nov 2020 13:59:20
User entered 'breaths/min'	System	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed query 'Per CDM: Response noted. Please Check 'Not done' box. Thank you.' (Site from DM).	(b) (4)	02 Dec 2020 04:19:08
Query 'Per CDM: Response noted. Please Check 'Not done' box. Thank you.' answered with "'ND" inserted per query ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:52:49
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	01 Dec 2020 15:52:27
User opened query 'Per CDM: Response noted. Please Check 'Not done' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:11:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Dec 2020 15:11:09
Query 'Data is required. Please provide.' answered with 'Screening and Visit Day is the same. Per CCG, "ND" should be selected' (Site from System).	(b) (4), (b) (6)	30 Nov 2020 14:00:20
User opened query 'Data is required. Please provide.' System (Site from System).		30 Nov 2020 13:59:20
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	30 Nov 2020 13:59:20
User entered '132'	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'mmHg'	System	01 Dec 2020 15:52:27
User entered empty.	System	30 Nov 2020 13:59:20
User entered 'mmHg'	System	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:00:17
Signature has been broken indirectly.	(b) (4)	02 Apr 2021 16:33:47
User signature succeeded.	System	19 Mar 2021 17:47:50
	Bindu Balani (b) (4)	
	(b) (4)	
User closed query 'Per CDM: Response noted. Please Check 'Not done' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 04:19:21
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 04:19:16
Query 'Per CDM: Response noted. Please Check 'Not done' box. Thank you.' answered with ""ND" inserted per query ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:52:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	01 Dec 2020 15:52:27
User opened query 'Per CDM: Response noted. Please Check 'Not done' box. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:11:25
Query 'Data is required. Please provide.' answered with 'Screening and Visit Day is the same. Per CCG, "ND" should be selected' (Site from System).	(b) (4), (b) (6)	30 Nov 2020 14:00:24
User opened query 'Data is required. Please provide.' System (Site from System).		30 Nov 2020 13:59:20
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	30 Nov 2020 13:59:20
User entered '92'	(b) (4), (b) (6)	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'mmHg'	System	01 Dec 2020 15:52:27
User entered empty.	System	30 Nov 2020 13:59:20
User entered 'mmHg'	System	14 Sep 2020 20:09:50

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:10:01

US3602037

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:10:01

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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: 10 Jun 2021 09:10:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (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: 10 Jun 2021 09:10:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:34

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:34

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:13:03

US3602037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:14:53

US3602037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:14:53

US3602037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:14:53

US3602037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'VISIT1'	System	13 Oct 2020 15:14:53

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '14 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 18:39:59

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '113927'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 18:39:59

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Sep 2020 18:39:59

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:15:12

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:15:12

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:15:12

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:15:12

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:15:12

US3602037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (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: 10 Jun 2021 09:10:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '13:50'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '84'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'bpm'	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '13'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'breaths/min'	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '132'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'mmHg'	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '92'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered 'mmHg'	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	13 Oct 2020 15:16:21

US3602037

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:30

US3602037

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:16:30

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:34

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed query ' Per CDM: Action taken with investigational product recorded as 'Investigational Product Withdrawn' on AE#1. However, If No, reason not given recorded as Withdrawal of Consent by Participant' here. Please confirm and update appropriately. Else clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 04:02:25
Query ' Per CDM: Action taken with investigational product recorded as 'Investigational Product Withdrawn' on AE#1. However, If No, reason not given recorded as Withdrawal of Consent by Participant' here. Please confirm and update appropriately. Else clarify. Thank you. ' answered with 'Subject declined due to A.E (vasovagal syncopal episode) ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 17:53:30
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Nov 2020 17:49:40
User opened query ' Per CDM: Action taken with investigational product recorded as 'Investigational Product Withdrawn' on AE#1. However, If No, reason not given recorded as Withdrawal of Consent by Participant' here. Please confirm and update appropriately. Else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 16:25:44
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	28 Sep 2020 15:43:46

US3602037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered empty.	System	28 Sep 2020 15:43:46

US3602037

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	14 Mar 2021 00:01:53
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Vasovagal reaction - version MedDRA\23.0.	Coder Import (b) (4)	23 Dec 2020 15:12:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Dec 2020 15:12:38
User closed query 'Per MM, please provide the 'Treatment 1 Date'	(b) (4), (b) (6)	02 Dec 2020 09:25:55
' (Site from DM).		
Query 'Per MM, please provide the 'Treatment 1 Date'	(b) (4), (b) (6)	01 Dec 2020 15:51:25
' answered with 'Please provide clarification on what "Treatment 1 Date" is, because subject did NOT receive IP dose #1 or dose #2.		
Is "Treatment 1 Date", the date that the subject came in for randomization? If so, it is September 14th, 2020. Please advise. Thank you.' (Site from DM).		
User opened query 'Per MM, please provide the 'Treatment 1 Date'	(b) (4), (b) (6)	01 Dec 2020 06:22:53
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:45:58
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Vasovagal attack - version MedDRA\23.0.	Coder Import (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)	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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:45:58
User closed query 'Start time is present for an AE that System did not start within 24 hours after dosing. Please remove the Start time.' (Site from 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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:15:24
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:31:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)' 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 '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: 10 Jun 2021 09:10:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:15:27
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4) 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: 10 Jun 2021 09:10:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:15:34
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Un-verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:15:37
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Un-verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:15:38
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Un-verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:15:41
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	17 Nov 2020 16:31:40
DataPoint Un-verified.	(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).	System	17 Nov 2020 16:31:18
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: 10 Jun 2021 09:10:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:15:43
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
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: 10 Jun 2021 09:10:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:34
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[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: 10 Jun 2021 09:10:34

[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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered '0'	System	13 Oct 2020 15:21:17

US3602037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Un-verified.	(b) (4) (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: 10 Jun 2021 09:10:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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)	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)	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)	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)	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: 10 Jun 2021 09:10:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (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: 10 Jun 2021 09:10:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed 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) (4), (b) (6)	25 Nov 2020 17:47:32
(Site from DM).		
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: 10 Jun 2021 09:10:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'unknown'	(b) (4) (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: 10 Jun 2021 09:10:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Other (OTHER)'	(b) (4) (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: 10 Jun 2021 09:10:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'unknown'	(b) (4) (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: 10 Jun 2021 09:10:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'as needed (PRN)'	(b) (4) (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: 10 Jun 2021 09:10:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (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: 10 Jun 2021 09:10:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Oral (ORAL)'	(b) (4) (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: 10 Jun 2021 09:10:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (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: 10 Jun 2021 09:10:34

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'UN UNK 2015'	(b) (4) (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: 10 Jun 2021 09:10:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (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: 10 Jun 2021 09:10:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (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: 10 Jun 2021 09:10:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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)	01 Dec 2020 21:38:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 21:38:54
Data point term sent to Coder	System	01 Dec 2020 21:37:48
Coding entries removed.	(b) (4), (b) (6)	01 Dec 2020 21:37:23
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: 10 Jun 2021 09:10:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (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: 10 Jun 2021 09:10:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (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) (4), (b) (6)	04 Dec 2020 16:21:21
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. ' answered with 'Indication updated and medical condition added to medical history' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:37:52
User entered 'Insomnia' reason for change: New Information	(b) (4), (b) (6)	01 Dec 2020 21:37:23
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: 10 Jun 2021 09:10:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '50' reason for change: New Information	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:47:29
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: 10 Jun 2021 09:10:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'mg (mg)'	(b) (4) (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: 10 Jun 2021 09:10:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (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: 10 Jun 2021 09:10:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'once daily (QD)'	(b) (4) (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: 10 Jun 2021 09:10:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (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: 10 Jun 2021 09:10:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Oral (ORAL)'	(b) (4) (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: 10 Jun 2021 09:10:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (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: 10 Jun 2021 09:10:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '01 Jan 2010' reason for change: New Information	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:47:29
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: 10 Jun 2021 09:10:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '0'	(b) (4) (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: 10 Jun 2021 09:10:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'Yes (Y)'	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User entered '804 (804)'	System	13 Oct 2020 16:03:27

US3602037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:10:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 03:56:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:03:37

US3602037

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:10:34

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:48:40
User closed query 'Data is required. Please complete this page.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 16:48:37
Query 'Data is required. Please complete this page.' answered with 'Entry updated per query. Thank you.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 16:13:39
User entered '25 Sep 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Apr 2021 16:13:25
User opened query 'Data is required. Please complete this page.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:51:22
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 15:49:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 14:55:23
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Apr 2021 10:56:16
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 10:56:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:08:19
User closed query 'Subject was randomized but not dosed in PART A of the study. Dosing was discontinued. This page must be completed.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 23:08:17
Query 'Subject was randomized but not dosed in PART A of the study. Dosing was discontinued. This page must be completed.' answered with 'Subject never received a dose in PART A. Form was completed in error. Please inactivate. Thank you.' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 20:11:28
User opened query 'Subject was randomized but not dosed in PART A of the study. Dosing was discontinued. This page must be completed.' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 19:42:24
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 16:27:59
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 03:55:42

US3602037

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:10:34

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Completed per the request of (b) (6)	(b) (4), (b) (6)	04 Mar 2021 05:11:03
(b) (6) - Sr. Remote Site Monitor via email saying "Please delete the data entered on the End of Study "Dosing Discontinuation Page" as they did receive Dose 1 during the Blinded Phase." Thank you.' (Site from System).	(b) (4), (b) (6)	03 Mar 2021 19:03:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 19:01:55
User entered empty; reason for change New Information	(b) (4), (b) (6)	03 Mar 2021 19:01:55
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: 10 Jun 2021 09:10:34

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:48:40
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Apr 2021 16:13:25
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 15:51:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 14:55:23
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Apr 2021 10:56:16
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 10:56:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:08:19
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 16:28:02
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 03:55:42
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 05:11:01
Query 'Data is required. Please complete.' answered with 'Completed per the request of (b) (6) (b) (6) - Sr. Remote Site Monitor via email saying "Please delete the data entered on the End of Study "Dosing Discontinuation Page" as they did receive Dose 1 during the Blinded Phase." Thank you.' (Site from System).	(b) (4), (b) (6)	03 Mar 2021 19:03:09
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 19:01:55
User entered empty; reason for change New Information	(b) (4), (b) (6)	03 Mar 2021 19:01:55
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	09 Apr 2021 01:50:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:48:40
User entered 'AE #1' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Apr 2021 16:13:25
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 15:51:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 14:55:23
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Apr 2021 10:56:16
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 10:56:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:08:19
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 16:28:42
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 03:55:42
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 05:10:58
User entered empty; reason for change New Information	(b) (4), (b) (6)	03 Mar 2021 19:01:55
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'Updated per query resolution request.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 17:40:38
User entered 'AE #1' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Mar 2021 17:40:25
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:08:23

US3602037

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:10:34

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 sponsor review, please consider updated field with only number. (i.e. #1). Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 05:02:03
Query 'Per sponsor review, please consider updated field with only number. (i.e. #1). Thank you.' answered with 'Updated entry as "#1" per query resolution suggestion. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 20:16:22
User entered '#1' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Feb 2021 20:16:01
User opened query 'Per sponsor review, please consider updated field with only number. (i.e. #1). Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:09:27
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

US3602037

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Query 'Per CDM: Please 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: 10 Jun 2021 09:10:34

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 03:55:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
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) (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: 10 Jun 2021 09:10:34

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 03:55:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:22:56

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 03:55:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 05:11:15
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you.' answered with 'Updated per query resolution.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 17:40:08
User entered 'AE #1' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Mar 2021 17:39:57
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:08:30
User closed query 'Per sponsor review, please consider updating field to only include number. (i.e. #1). Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 05:01:41
Query 'Per sponsor review, please consider updating field to only include number. (i.e. #1). Thank you.' answered with 'Updated entry to "#1" per query resolution suggestion. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 20:17:08
User entered '#1' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Feb 2021 20:16:43
User opened query 'Per sponsor review, please consider updating field to only include number. (i.e. #1). Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:10:33
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

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
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.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:42:20
User entered 'AE Log Line 1	(b) (4), (b) (6)	10 Nov 2020 21:42:12
AEID: USA-US079-2020-MRNA-1273-P301000002 reason for change: Per Query Resolution		
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 03:55:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:22:56

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:10:34

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 03:55:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:22:56

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:10:34

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 03:55:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:22:56

US3602037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:10:34

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 03:55:57
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered empty.	(b) (4) (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: 10 Jun 2021 09:10:34

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 09:10:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 09:10:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:34

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:34

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:34

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 09:10:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
Reviewed for Safety.	(b) (4)	
	(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: 10 Jun 2021 09:10:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:34

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:34

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:34

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:16:25
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '14/Oct/2020 08:19'	(b) (4) System	14 Oct 2020 12:19:37

US3602037

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

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:16:25
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 21:38:55
User entered 'I'	(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: 10 Jun 2021 09:10:34

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 09:10:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 09:10:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:34

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:34

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:34

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:16:25
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '29/Oct/2020 17:39'	(b) (4) System	29 Oct 2020 21:39:11

US3602037

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

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:16:25
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:27:33
User entered 'I'	(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: 10 Jun 2021 09:10:34

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 09:10:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 09:10:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:34

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:34

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30

US3602037

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:34

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
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: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:16:25
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered '13/Nov/2020 14:27'	(b) (4) System	13 Nov 2020 14:27:49

US3602037

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

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:10:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:16:25
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:47:50
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 14:27:49