

US3482145 (Prod: Hope Clinic of The Emory Vaccine Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:47:49

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US3482145

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 23:13:25

Generated On: 09 Jun 2021 17:47:49

Participant ID

US3482145

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

US3482145

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 15:25:57

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Date of Informed Consent (<i>dd MMM yyyy</i>)	26 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 15:25:57

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 15:25:57

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Condition	RHEUMATIC FEVER ATRIAL FIBRILLATION. DETAILS: HOSPITALIZED AT ENGLESTON- 1964
Start date (dd MMM yyyy)	UN UNK 1964
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1964
Start Year (derived)	1964
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Condition	RIGHT KNEE INJURY. DETAILS: WEARS A KNEE BRACE AT HOME AND USES A CANE WHILE WALKING.
Start date (dd MMM yyyy)	UN FEB 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)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Condition	GOUT IN BILATERAL KNEES
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Condition	WATER RETENTION IN FEET RELATED TO GOUT.
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Condition	CHRONIC SYSTOLIC HEART FAILURE.
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)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
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)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Condition	CHRONIC KIDNEY DISEASE STAGE III
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)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Condition	MACROCYTIC ANEMIA
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)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Condition	CORONARY ARTERY DISEASE
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)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:00 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:00
Height (<i>xxx.x</i>)	71 in
Weight (<i>xxx.x</i>)	188 lb
BMI (<i>xxx.x</i>)	26.27550 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:25:57

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:25:57

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:25:57

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:25:57

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 15:25:57

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What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 188417

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

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☒ No ☐

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

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)	26 AUG 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:00
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 13:30
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 26 AUG 2020

What was the treatment time? (00:00-23:59) 12:55 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 12:55

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:25:57

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Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 AUG 2020
Collection time (00:00-23:59)	12:20 (24 HR)
Collection date and time (derived)	26 AUG 2020 12:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:25	26 AUG 2020 12:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

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

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 13:31

PC Open Date & Time

26 AUG 2020 13:15

PC Close Date & Time

26 AUG 2020 15:45

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

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

PC Time Stamp	27 AUG 2020 11:53
PC Open Date & Time	26 AUG 2020 16:40
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 21:49

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 23:28

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 00:12

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 10:09

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 13:32

PC Open Date & Time

26 AUG 2020 13:15

PC Close Date & Time

26 AUG 2020 15:45

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 11:57

PC Open Date & Time

26 AUG 2020 16:40

PC Close Date & Time

27 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 21:52

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 13:33
PC Open Date & Time	26 AUG 2020 13:15
PC Close Date & Time	26 AUG 2020 15:45

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☒
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☒
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☒
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 11:55
PC Open Date & Time	26 AUG 2020 16:40
PC Close Date & Time	27 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 21:51
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 3015

EAB) (1725)

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 23:30
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 00:15
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☒

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 3015

EAB) (1725)

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 10:11
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

62 of 3015

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

Yes ☐

PC Time stamp

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

Yes ☐

PC Time stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3482145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482145

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 SEP 2020

Please select one status for the follow-up contact
Contact Made ☐
Contact Not Made ☒

Comments CONTACT ATTEMPTED ON
SEPTEMBER 9,10, AND 11.
If Contact Not Made, please provide Comments FOUND OUT SUBJECT WAS
HOSPITALIZED, SAE FILLED

US3482145

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

Please select one status for the follow-up contact
Contact Made ☐
Contact Not Made ☒

Comments CONTACT ATTEMPTED ON
SEPTEMBER 16,18,21, AND 22.
UNABLE TO REACH
PARTICIPANT. CALLED
SECONDARY CONTACT, NO
ANSWER EITHER.

If Contact Not Made, please provide Comments

US3482145

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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	VISIT2

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

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)	23 SEP 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:15
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

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	

US3482145

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3482145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

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

SAE FILLED AFTER HOSPITALIZATION. SUBJECT HAS UNSTABLE MEDICAL CONDITIONS, INCLUSION CRITERIA NOT MET.

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? _____

US3482145

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

10:40 (24 HR)

Collection date and time (derived)

23 SEP 2020 10:40

US3482145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:35	23 SEP 2020 10:35
Nasopharyngeal Swab 2	No		

US3482145

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482145

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482145

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482145

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT3

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3482145

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3482145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3482145

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:25:57

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 89

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

20 NOV 2020 13:35:38

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

04 DEC 2020 06:48:30

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 124

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

26 DEC 2020 18:44:59

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

05 JAN 2021 06:12:18

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

11 JAN 2021 01:31:07

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 152

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

22 JAN 2021 00:35:12

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 159

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

31 JAN 2021 04:21:09

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

07 FEB 2021 01:14:01

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

12 FEB 2021 02:26:48

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 180

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 FEB 2021 00:40:26

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 187

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

01 MAR 2021 03:27:16

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 194

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

09 MAR 2021 01:10:35

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 201

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

16 MAR 2021 01:05:54

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

26 MAR 2021 22:33:59

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

02 APR 2021 14:44:56

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	08 OCT 2021 00:01
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Patient Cloud Close Date & Time	12 OCT 2021 23:59
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US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	03 DEC 2021 00:01
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Patient Cloud Close Date & Time	07 DEC 2021 23:59
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US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 488

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JAN 2022 00:01
Patient Cloud Close Date & Time	11 JAN 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 537
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 APR 2022 00:01
Patient Cloud Close Date & Time	05 APR 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2022 00:01
Patient Cloud Close Date & Time	21 JUN 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2022 00:01
Patient Cloud Close Date & Time	02 AUG 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	19 AUG 2022 00:01
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Patient Cloud Close Date & Time	23 AUG 2022 23:59
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US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	14 OCT 2022 00:01
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Patient Cloud Close Date & Time	18 OCT 2022 23:59
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US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3482145

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:47:49

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		09 MAR 2021 07:03:30

US3482145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 NOV 2020

Please select one status for the follow-up contact
Contact Made ☐
Contact Not Made ☒

Comments
If Contact Not Made, please provide Comments
PROTOCOL DEVIATION
COMPLETED, SUBJECT PAID
PHONE BILL TO ALLOW
FUTURE COMMUNICATION

US3482145

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482145

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482145

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 FEB 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482145

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	22 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3482145

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3482145

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	09:20 (24 HR)
Collection date and time (derived)	22 MAR 2021 09:20

US3482145

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482145

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3482145

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:47:49

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

US3482145

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:47:49

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3482145

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3482145

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:14:06

Generated On: 09 Jun 2021 17:47:49

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3482145

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3482145

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	22 JAN 2021
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 12:06
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3482145

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 13:05
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3482145

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

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 JAN 2021

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

US3482145

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

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 12:35 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 12:35

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

What was the frequency of the study treatment dosing? ONCE

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

US3482145

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

14:45 (24 HR)

Collection date and time (derived)

14 JAN 2021 14:45

US3482145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	15:00
Collection Date and Time (derived)	14 JAN 2021 15:00

US3482145

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

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482145

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3482145

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:13:25

Generated On: 09 Jun 2021 17:47:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 23:13:25

Generated On: 09 Jun 2021 17:47:49

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)	19 FEB 2021
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 14:21
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 23:13:25

Generated On: 09 Jun 2021 17:47:49

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 15:20
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3482145

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:13:25

Generated On: 09 Jun 2021 17:47:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3482145

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 23:13:25

Generated On: 09 Jun 2021 17:47:49

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 FEB 2021

What was the treatment time? (00:00-23:59) 14:50 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 14:50

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

What was the frequency of the study treatment dosing? ONCE

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

US3482145

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:13:25

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482145

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482145

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3482145

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:13:26

Generated On: 09 Jun 2021 17:47:49

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3482145

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:13:25

Generated On: 09 Jun 2021 17:47:49

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3482145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:13:25

Generated On: 09 Jun 2021 17:47:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	22 MAR 2021
Collection time (<i>00:00-23:59</i>)	09:20 (24 HR)
Collection date and time (derived)	22 MAR 2021 09:20

US3482145

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

AEID	USA-US106-2020-MRNA-1273-P30 1000001
Adverse event	SEPSIS RELATED TO STREPTOCOCCUS BACTEREMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 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)	13 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	2 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	13 SEP 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

Number of Days in ICU	3
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
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 _____	

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

SUBJECT, WITH A PAST
MEDICAL HISTORY
SIGNIFICANT FOR CHRONIC
SYSTOLIC HEART FAILURE
WITH EJECTION FRACTION OF
25% WAS ADMITTED TO THE
EMERGENCY DEPARTMENT ON
09/02/2020 FOR ALTERED
MENTAL STATUS,
BACTEREMIA, AND ACUTE
CARDIAC HEART FAILURE
EXACERBATION. PATIENT
PRESENTED WITH: -WBC
COUNT: 13.L 10E3/MCL
LACTIC ACID: 3.6 MMOL/L
BNP: <4700 PG/ML
COVID BY PCR ON 09/02/2020:
NEGATIVE
URINE CULTURE: POSITIVE
<10,000 CFU/ML
EJECTION FRACTION ON
ECHOCARDIOGRAM: 25%-30%
BLOOD CULTURE: POSITIVE
FOR BETA HEMOLYTIC
STREPTOCOCCUS GROUP C.
SUBJECT TREATED WITH
CEFTRIAXONE THEN SHIFTED
TO LEVOFLOXACIN (COURSE
DONE ON SEP 16).
VITALS ON ADMISSION: T: 37.8°
ORAL. BP: 105/72 MMHG, HR: 75
BPM, SPO2: 100%.
PHYSICAL EXAM ON
ADMISSION TO ED:
HEENT: NORMOCEPHALIC,

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

ATRAUMATIC, PUPILS
EQUALLY ROUND AND
REACTIVE TO LIGHT, NO JVD,
NO LYMPHADENOPATHY.
LUNGS: CLEAR TO
AUSCULTATION BILATERALLY.
CVS: IRREGULAR RATE AND
RHYTHM, NO MURMURS OR
RUBS.
ABD: NABS, SOFT, NONTENDER,
NON DISTENDED.
EXT: NO CLUBBING, NO
CYANOSIS, +2 EDEMA OF
LOWER EXTREMITIES
BILATERALLY.
NEURO: ALERT AND ORIENTED
TO PERSON, PLACE, AND
SITUATION. LETHARGIC BUT
AROUSABLE, NO FOCAL
NEUROLOGIC DEFICITS.

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

US3482145

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

AEID	USA-US106-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE CARDIAC HEART FAILURE EXACERBATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 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)	13 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	02 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	13 SEP 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

Number of Days in ICU	3
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
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	

US3482145

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

SUBJECT, WITH A PAST
MEDICAL HISTORY
SIGNIFICANT FOR CHRONIC
SYSTOLIC HEART FAILURE
WITH EJECTION FRACTION OF
25% WAS ADMITTED TO THE
EMERGENCY DEPARTMENT ON
09/02/2020 FOR ALTERED
MENTAL STATUS,
BACTEREMIA, AND ACUTE
CARDIAC HEART FAILURE
EXACERBATION. PATIENT
PRESENTED WITH: -WBC
COUNT: 13.L 10E3/MCL
LACTIC ACID: 3.6 MMOL/L
BNP: <4700 PG/ML
COVID BY PCR ON 09/02/2020:
NEGATIVE
URINE CULTURE: POSITIVE
<10,000 CFU/ML
EJECTION FRACTION ON
ECHOCARDIOGRAM: 25%-30%
BLOOD CULTURE: POSITIVE
FOR BETA HEMOLYTIC
STREPTOCOCCUS GROUP C.
SUBJECT TREATED WITH
CEFTRIAZONE THEN SHIFTED
TO LEVOFLOXACIN (COURSE
DONE ON SEP 16).
VITALS ON ADMISSION: T: 37.8°
ORAL. BP: 105/72 MMHG, HR: 75
BPM, SPO2: 100%.
PHYSICAL EXAM ON
ADMISSION TO ED:
HEENT: NORMOCEPHALIC,

US3482145

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

ATRAUMATIC, PUPILS
EQUALLY ROUND AND
REACTIVE TO LIGHT, NO JVD,
NO LYMPHADENOPATHY.
LUNGS: CLEAR TO
AUSCULTATION BILATERALLY.
CVS: IRREGULAR RATE AND
RHYTHM, NO MURMURS OR
RUBS.
ABD: NABS, SOFT, NONTENDER,
NON DISTENDED.
EXT: NO CLUBBING, NO
CYANOSIS, +2 EDEMA OF
LOWER EXTREMITIES
BILATERALLY.
NEURO: ALERT AND ORIENTED
TO PERSON, PLACE, AND
SITUATION. LETHARGIC BUT
AROUSABLE, NO FOCAL
NEUROLOGIC DEFICITS.

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

US3482145

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

AEID	USA-US106-2020-MRNA-1273-P30 1000005
Adverse event	EXACERBATION OF ANEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 OCT 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)	26 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	26 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

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 checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input 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	

US3482145

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

NARRATIVE OBTAINED FROM
PHYSICIAN CONSULT NOTE AT
ADMINISSON. PATIENT IS A 66
YEAR OLD MAN WITH A PAST
MEDICAL HISTORY OF
CONGESTIVE HEART FAILURE,
HYPERTENSION, AND
CORONARY ARTERY DISEASE
WHO HAS BEEN HAVING
MELENA AND FATIGUE SINCE
EARLIER IN THE WEEK. THE
PATIENT STATES HE HAD AN
EDG AND COLONOSCOPY
PERFORMED 3-6 MONTHS AGO
AT EMORY MIDTOWN
HOSPITAL. HE STATES THAT
THESE RESULTS WERE
NORMAL. HE ALSO STATES
THAT THE PROCEDURES WERE
DONE AT THE SAME TIME
BECAUSE HE WAS HAVING
FATIGUE AND NOT BECAUSE
HE WAS HAVING MELENA.
10/21/20: PATIENT CAME TO
THE ED AND WAS NOTED ON
LABS TO HAVE A BUN/CR OF
68/1.0. HEMOGLOBIN WAS
NOTED TO BE 6.6G/DL.
FOLLOW UP HEMOGLOBIN
WAS NOTED TO BE 6.3G/DL,
FERRITIN LEVEL: 78NG/ML
FOLATE LEVEL: 9.7 NG/ML,
TOTAL IRON LEVEL: 36UG/DL
CXR SHOWEDCARDIOMEALY
WITH INTACT METALLIC

US3482145

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

PROSTHETIC VALVE. PATIENT STATES THAT HE HAS HAD A VALVE REPLACEMENT IN THE PAST. 10/21 EKG SHOWS AFIB AND T-WAVE INVERSION IN LEADS I,II, V2, V45-V6. TROP NEGATIVE. GI CONSULTED FOR GI BLEED. PATIENT STARTED ON PROTONIX BOLUS AND DRIP. RECEIVED 3 UNITS OF BLOOD WHILE HOSPITALIZED. COVID 19 TESTING BY PCR DONE ON 10/22/2020 IS NEGATIVE.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

AEID	USA-US106-2020-MRNA-1273-P30 1000006
Adverse event	GOUT EXACERBATION IN RIGHT KNEE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 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)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	30 SEP 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Number of Days in ICU	3
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input 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	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

SUBJECT WENT TO THE
EMERGENCY DEPARTMENT
COMPLAINING OF RIGHT KNEE
PAIN AND SWELLING
AFFECTING HIS ABILITY TO
AMBULATE. PATIENT
PRESENTED WITH ELEVATED
LEVELS OF URIC ACID (10.5
MG/DL), DIAGNOSED WITH
ACUTE GOUT FLARE,
IMPROVED ON PREDNISONE.
SUBJECT WAS ALSO FOUND TO
HAVE ACUTE EXACERBATION
OF STAGE III KIDNEY DISEASE,
HYPERKALEMIA, AND
ACIDOSIS PH: 7.14, LACTATE
2.51.

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

AEID	USA-US106-2020-MRNA-1273-P30 1000006
Adverse event	ACUTE EXACERBATION OF CHRONIC KIDNEY DISEASE STAGE III
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 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)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	30 SEP 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 03:17:50

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	Unknown	<input type="radio"/>
Number of Days in ICU		3
Persistent or significant disability or incapacity		False
Congenital anomaly or birth defect		False
Other medically important event		False
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
Other action taken (check all that apply)		
None		False
Concomitant Medication		True
Concomitant Procedure		False
Outcome	Fatal	<input 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		

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

SUBJECT WENT TO THE
EMERGENCY DEPARTMENT
COMPLAINING OF RIGHT KNEE
PAIN AND SWELLING
AFFECTING HIS ABILITY TO
AMBULATE. PATIENT
PRESENTED WITH ELEVATED
LEVELS OF URIC ACID (10.5
MG/DL), DIAGNOSED WITH
ACUTE GOUT FLARE,
IMPROVED ON PREDNISONE.
SUBJECT WAS ALSO FOUND TO
HAVE ACUTE EXACERBATION
OF STAGE III KIDNEY DISEASE,
HYPERKALEMIA (POSTASSIUM
LEVEL: 8.4 MMOL/L), AND
ACIDOSIS PH: 7.14, LACTATE
2.51.

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

AEID	USA-US106-2020-MRNA-1273-P30 1000004
Adverse event	WORSENING OF ACUTE DECOMPENSATED HEART FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 NOV 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)	10 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	10 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 03:17:50

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 03:17:50

Generated On: 09 Jun 2021 17:47:49

SUBJECT PRESENTED TO ED ON
11/9/2020 WITH SHORTNESS OF
BREATH AND FELT LIKE HE
HAD A LOT OF FLUID ON HIM.
AFTER ADMISSION HE WAS
GIVEN IV FUROSEMIDE ON 11/9
AND 11/10 AND WAS FEELING
BETTER. COVID PCR NEGATIVE
ON 09NOV2020.
TROPONIN:0.03
BNP: 758
CR: 1.83, DROPPED TO 1.6.
NORMAL EKG READING

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 22:26:02

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication ATORVASTATIN CALCIUM

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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	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 2019	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication WATER RETENTION IN FEET
RELATED TO GOUT

Dose per administration 40

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intraocular	<input type="checkbox"/>
	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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENTION

Dose per administration 10

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication COLCHICINE

Prophylaxis Yes ☐
No ☒

Indication GOUT IN BOTH KNEES

Dose per administration 0.6

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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	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)	26 AUG 2020	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC SYSTOLIC HEART
FAILURE

Dose per administration 3.125

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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	Intraocular	<input type="checkbox"/>
	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) _____		
Start date completely unknown		True
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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 81

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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	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) _____		
Start date completely unknown		True
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication SEPSIS DUE TO BETA
HEMOLYTIC STREPTOCOCCUS
BACTEREMIA

Dose per administration 2

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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	Intraocular	<input type="checkbox"/>
	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 checked="" 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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication MACROCYTIC ANEMIA

Dose per administration 325

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	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) _____		
Start date completely unknown		True
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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication FLUTICASONE- SALMETEROL
HFA 230/21

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 2

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication DEEP VEIN THROMBOSIS
PROPHYLAXIS

Dose per administration 5000

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

If dose unit is Other, specify UNITS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intraocular	<input type="checkbox"/>
	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) _____		
Start date completely unknown		True
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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☒
No ☐

Indication ULCER PROPHYLAXIS

Dose per administration 40

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	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)		05 SEP 2020
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication ANALGESIA

Dose per administration 325

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

EVERY 6 HOURS AS NEEDED.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	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) _____		
Start date completely unknown		True
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication ANALGESIA

Dose per administration 650

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

EVERY 4 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	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 checked="" 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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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)		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication SEPSIS DUE TO BETA
HEMOLYTIC STREPTOCOCCUS
BACTEREMIA

Dose per administration 500

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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	Intraocular	<input type="checkbox"/>
	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)	13 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication ELECTROLYTE REPLACEMENT
RELATED TO CHRONIC
SYSTOLIC HEART FAILURE

Dose per administration 40

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

If dose unit is Other, specify MILLIEQUIVALENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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	Intraocular	<input type="checkbox"/>
	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)	05 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication THIAMINE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC SYSTOLIC HEART
FAILURE

Dose per administration 100

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intraocular	<input type="checkbox"/>
	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 checked="" 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)		03 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication AMPICILLIN- SULBACTAM

Prophylaxis Yes ☐
No ☒

Indication SEPSIS DUE TO BETA
HEMOLYTIC STREPTOCOCCUS
BACTEREMIA

Dose per administration 3

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	04 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC SYSTOLIC HEART FAILURE

Dose per administration 80

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

FOR 3 DOSES

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intraocular	<input type="checkbox"/>
	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 checked="" 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)		03 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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Name of Medication CALCIUM GLUCONATE

Prophylaxis Yes ☐
No ☒

Indication ACUTE EXACERBATION OF
CHRONIC KIDNEY DISEASE
STAGE III

Dose per administration 1

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intraocular	<input type="checkbox"/>
	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 checked="" 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)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication DEXTROSE 50% IN WATER

Prophylaxis Yes ☐
No ☒

Indication HYPERKALEMIA RELATED TO
ACUTE EXACERBATION OF
CHRONIC KIDNEY DISEASE
STAGE III

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	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 checked="" 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)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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Name of Medication REGULAR INSULIN

Prophylaxis Yes ☐
No ☒

Indication HYPERKALEMIA RELATED TO
ACUTE EXACERBATION OF
CHRONIC KIDNEY DISEASE
STAGE III

Dose per administration 10

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

If dose unit is Other, specify UNITS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	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 checked="" 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)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication LIDOCAINE TOPICAL PATCH 5%

Prophylaxis Yes ☐
No ☒

Indication GOUT EXACERBATION IN
RIGHT KNEE

Dose per administration 1

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

If dose unit is Other, specify PATCH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intraocular	<input type="checkbox"/>
	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)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication GOUT EXACERBATION IN
RIGHT KNEE

Dose per administration 40

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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	Intraocular	<input type="checkbox"/>
	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)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication SODIUM BICARBONATE

Prophylaxis Yes ☐
No ☒

Indication ACIDOSIS RELATED TO ACUTE
EXACERBATION OF CHRONIC
KIDNEY DISEASE STAGE III

Dose per administration 650

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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	Intraocular	<input type="checkbox"/>
	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 checked="" 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)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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Name of Medication SODIUM POLYSTYRENE
SULFONATE (KAYEXELATE)

Prophylaxis Yes ☐
No ☒

Indication HYPERKALEMIA RELATED TO
ACUTE EXACERBATION OF
CHRONIC KIDNEY DISEASE
STAGE III

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Mar 2021 22:26:01

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	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	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)	27 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication INFLUENZA VIRUS VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		30 SEP 2020
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"/>

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication IRON

Prophylaxis Yes ☐
No ☒

Indication ACUTE DECOMPENSATED
HEART FAILURE

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intraocular	<input type="checkbox"/>
	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 checked="" 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)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication SHORTNESS OF BREATH DUE
TO ACUTE DECOMPENSATED
HEART FAILURE

Dose per administration 40

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intraocular	<input type="checkbox"/>
	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 checked="" 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)	09 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication PACKED RED BLOOD CELLS

Prophylaxis Yes ☐
No ☒

Indication SAE: EXACERBATION OF ANEMIA

Dose per administration 1

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

If dose unit is Other, specify UNIT

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 ☐

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intraocular	<input type="checkbox"/>
	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

Name of Medication OMEPRAZOLE (PROTONIX)

Prophylaxis Yes ☐
No ☒

Indication AE#3: EXACERBATION OF ANEMIA

Dose per administration UNK

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Mar 2021 22:26:01

Generated On: 09 Jun 2021 17:47:49

	Intraocular	<input type="checkbox"/>
	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 checked="" 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)	21 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 SEP 2020	ECHOCARDIOGROPHAY	Diagnostic	
02 SEP 2020	BLOOD CULTURE	Adverse Event	
02 SEP 2020	URINE CULTURE	Adverse Event	
02 SEP 2020	BLOOD WORKUP	Adverse Event	
23 OCT 2020	DIAGNOSTIC COLONOSCOPY	Adverse Event	
21 OCT 2020	BLOOD WORKUP	Adverse Event	
22 OCT 2020	BLOOD WORKUP	Adverse Event	
21 OCT 2020	CHEST X-RAY	Adverse Event	
21 OCT 2020	EKG	Adverse Event	

US3482145

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 01 Apr 2021 23:13:25

Generated On: 09 Jun 2021 17:47:49

Date of dosing discontinuation (dd MMM yyyy)	23 SEP 2020
--	-------------

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

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

DOES NOT MEET INCLUSION
CRITERIA NUMBER 7

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:47:49

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	12/SEP/2020 17:11
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	15/SEP/2020 10:28
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	23/SEP/2020 10:54
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	23/SEP/2020 13:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	23/SEP/2020 22:05
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	06/OCT/2020 12:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	22/OCT/2020 18:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

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Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	23/OCT/2020 13:46
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	29/OCT/2020 16:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	03/NOV/2020 16:15
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	10/NOV/2020 09:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	10/NOV/2020 11:46
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (13)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	11/NOV/2020 15:16
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (14)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	12/NOV/2020 15:43
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (16)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	25/NOV/2020 19:16
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (17)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	22/DEC/2020 16:04
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	17/NOV/2020 12:20
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/NOV/2020 19:16
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/DEC/2020 10:36
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	14/JAN/2021 19:25
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	17/NOV/2020 12:21
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/DEC/2020 10:50
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/DEC/2020 14:29
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/JAN/2021 11:40
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	27/JAN/2021 11:20
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

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 22:26:02

Generated On: 09 Jun 2021 17:47:49

SAEID	USA-US106-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	17/NOV/2020 12:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3482145 (Prod: Hope Clinic of The Emory Vaccine Center)

US3482145

Form: Participant Creation

Generated On: 09 Jun 2021 17:47:49

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'US3482145'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:09:53

US3482145

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:35

US3482145

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:09:54

US3482145

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Clinic (Clinic)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:19:35

US3482145

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'SCRN'	System	26 Aug 2020 17:19:35

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:09:55

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '66'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:46

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'YEARS'	System	26 Aug 2020 17:19:46

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered '66'	System	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Male (M)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:46

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:46

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:19:46

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'I'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:19:46

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:46

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:19:46

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:19:46

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:19:46

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:46
	(b) (4)	

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:19:46

US3482145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:47:49

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:46

US3482145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:47:49

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '26 Aug 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'Aug 2020'	System	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered '2020'	System	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:47:49

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Amendment 2 (2)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:47:49

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:47:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:47:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:47:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:09:54

US3482145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:47:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'I'	System	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:53

US3482145

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:47:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:24:49

US3482145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:47:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Rheumatic fever, LLT: Rheumatic fever - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 13:28:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 13:28:45
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	08 Oct 2020 18:57:05
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	Sarah Bechnak (b) (4)	05 Oct 2020 13:21:13
' answered with 'Not requiring treatment as per subject. ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	04 Oct 2020 11:49:05
' (Site from DM).		
Data point term sent to Coder	System	26 Aug 2020 18:00:09
User entered 'Rheumatic fever atrial fibrillation. Details: Hospitalized at Englestone- 1964'	Sarah Bechnak (b) (4)	26 Aug 2020 17:59:28
	(b) (4)	

US3482145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'UN UNK 1964'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:59:28

US3482145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:59:28

US3482145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:59:28

US3482145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:59:28

US3482145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:59:28

US3482145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'Jan 1964'	System	26 Aug 2020 17:59:28

US3482145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered '1964'	System	26 Aug 2020 17:59:28

US3482145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Aug 2020 17:59:28

US3482145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Aug 2020 17:59:28

US3482145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:47:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Oct 2020 11:50:15
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 11:49:53
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Knee injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 11:51:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 11:51:51
Data point term sent to Coder	System	26 Aug 2020 18:00:12
User entered 'Right knee injury. Details: wears a knee brace at home and uses a cane while walking.'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:00:10

US3482145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'UN Feb 2020' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	28 Aug 2020 13:25:57
User entered 'un UNK 2020'	(b) (4)	
	Sarah Bechnak (b) (4)	26 Aug 2020 18:00:10
	(b) (4)	

US3482145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:00:10

US3482145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:00:10

US3482145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:00:10

US3482145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:00:10

US3482145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'Feb 2020'	System	28 Aug 2020 13:25:57
User entered 'Jan 2020'	System	26 Aug 2020 18:00:10

US3482145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered '2020'	System	26 Aug 2020 18:00:10

US3482145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Aug 2020 18:00:10

US3482145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Aug 2020 18:00:10

US3482145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:47:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Per DM CLR: Please specify the location and/or type of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:39:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:38:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:38:31
Data point term sent to Coder	System	22 Oct 2020 17:37:40
Coding entries removed.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:36:48
User entered 'GOUT IN BILATERAL KNEES' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:36:48
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:46:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:46:34
Data point term sent to Coder	System	21 Oct 2020 19:45:45
Query 'Per DM CLR: Please specify the location and/or type of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'done' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	21 Oct 2020 19:45:20
Coding entries removed.	Sarah Bechnak (b) (4) (b) (4)	21 Oct 2020 19:45:09
User entered 'GOUT IN BILATERAL FEET' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	21 Oct 2020 19:45:09

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:47:49

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the location and/or type of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:57:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 17:58:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	27 Aug 2020 17:58:57
Data point term sent to Coder	System	26 Aug 2020 18:01:13
User entered 'Gout'	Sarah Bechnak (b) (4)	26 Aug 2020 18:00:31
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'UN UNK 2015'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:00:31

US3482145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:00:31

US3482145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:00:31

US3482145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:00:31

US3482145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:00:31

US3482145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'Jan 2015'	System	26 Aug 2020 18:00:31

US3482145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered '2015'	System	26 Aug 2020 18:00:31

US3482145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Aug 2020 18:00:31

US3482145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Aug 2020 18:00:31

US3482145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:47:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Aug 2020 17:58:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 17:58:56
Data point term sent to Coder	System	26 Aug 2020 18:01:16
User entered 'Hyperlipidemia'	Sarah Bechnak (b) (4)	26 Aug 2020 18:00:53
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'UN UNK 2019'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:00:53

US3482145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:00:53

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:00:53

US3482145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:00:53
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:00:53

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'Jan 2019'	System	26 Aug 2020 18:00:53

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered '2019'	System	26 Aug 2020 18:00:53

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Aug 2020 18:00:53

US3482145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Aug 2020 18:00:53

US3482145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:47:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Total fluid volume increased, PT: Fluid retention, LLT: Water retention in tissues - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 11:17:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 11:17:48
Data point term sent to Coder	System	26 Aug 2020 18:02:19
User entered 'Water retention in feet related to gout.'	Sarah Bechnak (b) (4)	26 Aug 2020 18:01:42

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'un UNK 2015'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:01:42

US3482145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:01:42

US3482145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:01:42

US3482145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:01:42

US3482145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:01:42

US3482145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'Jan 2015'	System	26 Aug 2020 18:01:42

US3482145

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered '2015'	System	26 Aug 2020 18:01:42

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Aug 2020 18:01:42

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Aug 2020 18:01:42

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:47:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Aug 2020 17:59:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:01
Data point term sent to Coder	System	26 Aug 2020 18:02:19
User entered 'Hypertension'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:02:17

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'UN UNK 2015'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:02:17

US3482145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:02:17

US3482145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:02:17

US3482145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 18:02:17

US3482145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:02:17

US3482145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'Jan 2015'	System	26 Aug 2020 18:02:17

US3482145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered '2015'	System	26 Aug 2020 18:02:17

US3482145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Aug 2020 18:02:17

US3482145

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Aug 2020 18:02:17

US3482145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:47:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Left ventricular failures, PT: Chronic left ventricular failure, LLT: Chronic systolic heart failure - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 06:02:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 06:02:41
Data point term sent to Coder	System	12 Sep 2020 00:45:20
User entered 'chronic systolic heart failure.'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:44:22

US3482145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 00:44:22

US3482145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'I'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:44:22

US3482145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 00:44:22

US3482145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 00:44:22

US3482145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:44:22

US3482145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:44:22

US3482145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:44:22

US3482145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:44:22

US3482145

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:44:22

US3482145

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:47:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 00:46:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 00:46:40
Data point term sent to Coder	System	12 Sep 2020 00:45:26
User entered 'Chronic obstructive pulmonary disease'	Sarah Bechnak (b) (4)	12 Sep 2020 00:44:49

US3482145

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 00:44:49

US3482145

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'I'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:44:49

US3482145

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:44:49

US3482145

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 00:44:49

US3482145

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:44:49

US3482145

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:44:49

US3482145

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:44:49

US3482145

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:44:49

US3482145

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:44:49

US3482145

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:47:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 00:50:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 00:50:39
Data point term sent to Coder	System	12 Sep 2020 00:50:01
User entered 'chronic kidney disease stage III'	Sarah Bechnak (b) (4)	12 Sep 2020 00:49:54
	(b) (4)	

US3482145

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 00:49:54

US3482145

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'I'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:49:54

US3482145

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:49:54

US3482145

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 00:49:54

US3482145

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:49:54

US3482145

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:49:54

US3482145

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:49:54

US3482145

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:49:54

US3482145

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:49:54

US3482145

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:47:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia macrocytic, LLT: Macrocytic anemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 00:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 00:51:40
Data point term sent to Coder	System	12 Sep 2020 00:51:01
User entered 'Macrocytic anemia'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:50:50

US3482145

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 00:50:50

US3482145

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'I'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:50:50

US3482145

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:50:50

US3482145

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 00:50:50

US3482145

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 00:50:50

US3482145

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:50:50

US3482145

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:50:50

US3482145

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:50:50

US3482145

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 00:50:50

US3482145

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:47:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Platelet disorders, HLT: Thrombocytopenias, PT: Thrombocytopenia, LLT: Thrombocytopenia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 05:07:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 05:07:49
Data point term sent to Coder	System	12 Sep 2020 02:02:20
User entered 'mild thrombocytopenia'	Sarah Bechnak (b) (4)	12 Sep 2020 02:01:31

US3482145

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 02:01:31

US3482145

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'I'	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 02:01:31

US3482145

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 02:01:31

US3482145

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 02:01:31

US3482145

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'I'	(b) (4) Sarah Bechnak (b) (4)	12 Sep 2020 02:01:31

US3482145

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 02:01:31

US3482145

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:47:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 02:01:31

US3482145

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 02:01:31

US3482145

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	12 Sep 2020 02:01:31

US3482145

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:47:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	26 Jan 2021 18:15:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 18:15:54
Data point term sent to Coder	System	26 Jan 2021 18:15:19
User entered 'coronary artery disease'	Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:15:12

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:15:12

US3482145

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'I'	Sarah Bechnak (b) (4)	26 Jan 2021 18:15:12

US3482145

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:15:12

US3482145

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:15:12

US3482145

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:15:12

US3482145

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Jan 2021 18:15:12

US3482145

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Jan 2021 18:15:12

US3482145

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Jan 2021 18:15:12

US3482145

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Jan 2021 18:15:12

US3482145

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:47:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Heart valve replacement, LLT: Heart valve replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:31:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:31:49
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	13 Feb 2021 15:25:58
Data point term sent to Coder	System	26 Jan 2021 18:46:59
User entered 'METALLIC PROSTHETIC HEART valve PLACEMENT' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:46:16
Data point term sent to Coder	System	26 Jan 2021 18:45:58
User entered 'metallic prosthetic heart placement'	Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:45:35

US3482145

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:45:35
	(b) (4)	

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Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'I'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:45:35

US3482145

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:47:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:45:35

US3482145

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:45:35

US3482145

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:47:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'I'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:45:35

US3482145

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Jan 2021 18:45:35

US3482145

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Jan 2021 18:45:35

US3482145

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Jan 2021 18:45:35

US3482145

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered empty.	System	26 Jan 2021 18:45:35

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '26 Aug 2020'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '11:00'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered '26 Aug 2020 11:00'	System	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '71' in	(b) (4)	
	Sarah Bechnak (b) (4)	26 Aug 2020 17:22:52
DataPoint set to visible.	(b) (4)	
	System	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '188' lb	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:22:52
DataPoint set to visible.	(b) (4) System	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
Amendment Manager: User entered '26.27550'	System	17 Sep 2020 00:03:32
User entered '26.3'	System	26 Aug 2020 17:22:52
DataPoint set to visible.	System	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'kg/m2'	System	26 Aug 2020 17:22:52
DataPoint set to visible.	System	26 Aug 2020 17:20:17

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Per CDM: Response noted; However as per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP in Vital sign Screening page. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 12:28:32
Query 'Per CDM: Response noted; However as per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP in Vital sign Screening page. Please update accordingly.' answered with 'updated to ND' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 17:19:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:19:10
User opened query 'Per CDM: Response noted; However as per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP in Vital sign Screening page. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 14:20:08
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 14:19:40
Query 'Data is required. Please provide.' answered with 'not required' (Site from System).	Sarah Bechnak (b) (4) (b) (4)	04 Sep 2020 16:28:00
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 17:22:52
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:19:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 14:19:41
Query 'Data is required. Please provide.' answered with 'not required' (Site from System).	Sarah Bechnak (b) (4) (b) (4)	04 Sep 2020 16:27:57
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 17:22:52
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'bpm'	System	08 Sep 2020 17:19:10
User entered empty.	System	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:19:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 14:19:43
Query 'Data is required. Please provide.' answered with 'not required' (Site from System).	Sarah Bechnak (b) (4) (b) (4)	04 Sep 2020 16:27:54
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 17:22:52
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'breaths/min'	System	08 Sep 2020 17:19:10
User entered empty.	System	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:19:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 14:19:44
Query 'Data is required. Please provide.' answered with 'not required' (Site from System).	Sarah Bechnak (b) (4) (b) (4)	04 Sep 2020 16:27:55
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 17:22:52
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'mmHg'	System	08 Sep 2020 17:19:10
User entered empty.	System	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:19:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 14:19:46
Query 'Data is required. Please provide.' answered with 'not required' (Site from System).	Sarah Bechnak (b) (4) (b) (4)	04 Sep 2020 16:27:52
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 17:22:52
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:22:52

US3482145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User entered 'mmHg'	System	08 Sep 2020 17:19:10
User entered empty.	System	26 Aug 2020 17:22:52

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:20:30

US3482145

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '26 Aug 2020'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:20:30
	(b) (4)	

US3482145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:21:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:21:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:21:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	Sarah Bechnak (b) (4)	26 Aug 2020 17:21:19

US3482145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:21:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

[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)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	Sarah Bechnak (b) (4)	26 Aug 2020 17:21:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	Sarah Bechnak (b) (4)	26 Aug 2020 17:21:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	Sarah Bechnak (b) (4)	26 Aug 2020 17:21:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

[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)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:21:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:21:19

US3482145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	Sarah Bechnak (b) (4)	26 Aug 2020 17:21:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:21:19
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:21:19
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:21:19

US3482145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:21:19

US3482145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	Sarah Bechnak (b) (4)	26 Aug 2020 17:21:19

US3482145

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:21:19

US3482145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '0'	Sarah Bechnak (b) (4)	26 Aug 2020 17:21:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'I'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:21:19

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'I'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:21:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:47:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:11:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Resident in a community with ongoing person to person transmission'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:21:19

US3482145

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:19:26

US3482145

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '26 Aug 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:19:26

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Clinic (Clinic)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:26

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'VISIT1'	System	26 Aug 2020 17:19:26

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 16:36:47

US3482145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '188417'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 16:36:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 16:36:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:47:49

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)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:12

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:47:49

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)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:12

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:12

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:47:49

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:12

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:47:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:19:12

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	22 Sep 2020 16:20:03
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 09:46:49
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:01:58

US3482145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 04:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	21 Sep 2020 17:30:48
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'DONE' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	21 Sep 2020 17:30:41
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 17:22:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 17:30:48
User entered empty.	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 04:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	21 Sep 2020 17:30:48
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'DONE' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	21 Sep 2020 17:30:41
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 17:22:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 17:30:48
User entered empty.	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User accepted default value 'Pre-Dose (PREDOSE)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '26 Aug 2020'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '11:00'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered '26 Aug 2020 11:00'	System	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	26 Aug 2020 17:23:39
data change (Site from System).		26 Aug 2020 17:23:39
User entered '97.8' F reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:39
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	26 Aug 2020 17:23:13
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:23:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	26 Aug 2020 17:23:48
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:48
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:23:39
User entered empty.	System	26 Aug 2020 17:23:13
	Sarah Bechnak (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:23:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	26 Aug 2020 17:23:39
User entered '81' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:39
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:23:13
User entered empty.	System	26 Aug 2020 17:23:13
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'bpm'	System	26 Aug 2020 17:23:39
User entered empty.	System	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:23:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	26 Aug 2020 17:23:39
User entered '16' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:39
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:23:13
User entered empty.	System	26 Aug 2020 17:23:13
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'breaths/min'	System	26 Aug 2020 17:23:39
User entered empty.	System	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:23:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	26 Aug 2020 17:23:39
User entered '123' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:39
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:23:13
User entered empty.	System	26 Aug 2020 17:23:13
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'mmHg'	System	26 Aug 2020 17:23:39
User entered empty.	System	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:23:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	26 Aug 2020 17:23:39
User entered '65' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:39
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:23:13
User entered empty.	System	26 Aug 2020 17:23:13
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'mmHg'	System	26 Aug 2020 17:23:39
User entered empty.	System	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 04:35:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	21 Sep 2020 17:30:48
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'DONE' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	21 Sep 2020 17:30:41
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 17:22:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 17:30:48
User entered empty.	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User accepted default value 'Post-Dose (POSTDOSE)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:54:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Aug 2020 17:54:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	26 Aug 2020 17:23:13
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	26 Aug 2020 17:54:45
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '13:30' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	26 Aug 2020 17:54:45
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered '26 Aug 2020 13:30'	System	26 Aug 2020 17:54:45
User entered empty.	System	26 Aug 2020 17:23:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:55:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	26 Aug 2020 17:55:15
User entered '97.8' F reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Aug 2020 17:55:15
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:54:45
User entered empty.	System	26 Aug 2020 17:54:45
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

US3482145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	26 Aug 2020 17:55:15
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

US3482145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:23:13

US3482145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:55:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	26 Aug 2020 17:55:15
User entered '61' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Aug 2020 17:55:15
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:54:45
User entered empty.	System	26 Aug 2020 17:54:45
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

US3482145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'bpm'	System	26 Aug 2020 17:55:15
User entered empty.	System	26 Aug 2020 17:23:13

US3482145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:55:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	26 Aug 2020 17:55:15
User entered '17' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Aug 2020 17:55:15
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:54:45
User entered empty.	System	26 Aug 2020 17:54:45
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

US3482145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'breaths/min'	System	26 Aug 2020 17:55:15
User entered empty.	System	26 Aug 2020 17:23:13

US3482145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:55:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	26 Aug 2020 17:55:15
User entered '136' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Aug 2020 17:55:15
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:54:45
User entered empty.	System	26 Aug 2020 17:54:45
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

US3482145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'mmHg'	System	26 Aug 2020 17:55:15
User entered empty.	System	26 Aug 2020 17:23:13

US3482145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:55:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	26 Aug 2020 17:55:15
User entered '73' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Aug 2020 17:55:15
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 17:54:45
User entered empty.	System	26 Aug 2020 17:54:45
	Sarah Bechnak (b) (4)	26 Aug 2020 17:23:13
	(b) (4)	

US3482145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'mmHg'	System	26 Aug 2020 17:55:15
User entered empty.	System	26 Aug 2020 17:23:13

US3482145

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:24:02

US3482145

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '26 Aug 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:24:02

US3482145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:21:44

US3482145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:21:44

US3482145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:21:44

US3482145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 17:21:44

US3482145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '26 Aug 2020'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:21:44

US3482145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '12:55'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:21:44

US3482145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered '26 Aug 2020 12:55'	System	26 Aug 2020 17:21:44

US3482145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Left Arm (LEFT ARM)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:21:44

US3482145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'ONCE'	System	26 Aug 2020 17:21:44

US3482145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 17:21:44

US3482145

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:24:18

US3482145

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '26 Aug 2020'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:24:18

US3482145

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '12:20'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:24:18

US3482145

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered '26 Aug 2020 12:20'	System	26 Aug 2020 17:24:18

US3482145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:47:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '26 Aug 2020'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:24:34

US3482145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:47:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:24:34

US3482145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:47:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:24:34

US3482145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:47:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '12:25'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:24:34

US3482145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered '26 Aug 2020 12:25'	System	26 Aug 2020 17:24:34

US3482145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:47:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 17:24:34

US3482145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:47:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:24:34

US3482145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:47:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:24:34

US3482145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:47:49

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered empty.	System	26 Aug 2020 17:24:34

US3482145

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Aug 2020 17:24:42

US3482145

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'I'	System	26 Aug 2020 17:24:42

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:31:06', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6277b284-024c-47f7-85f9-1b0486e7d216' User entered 'Yes (Y)'	System	26 Aug 2020 17:31:57
	System	26 Aug 2020 17:31:57

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:31:36', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6277b284-024c-47f7-85f9-1b0486e7d216' User entered '97.8'	System	26 Aug 2020 17:31:57
	System	26 Aug 2020 17:31:57

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:31:44', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6277b284-024c-47f7-85f9-1b0486e7d216' User entered 'No (N)'	System	26 Aug 2020 17:31:57
	System	26 Aug 2020 17:31:57

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:31:51', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6277b284-024c-47f7-85f9-1b0486e7d216' User entered '26 Aug 2020 13:31'	System	26 Aug 2020 17:31:57
	System	26 Aug 2020 17:31:57

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '26 Aug 2020 13:15'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '26 Aug 2020 15:45'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:52:37', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '464cf8d1-384c-4f89-8291-e3d63671c8b4' User entered 'Yes (Y)'	System	27 Aug 2020 15:53:19
	System	27 Aug 2020 15:53:19

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:52:03', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '464cf8d1-384c-4f89-8291-e3d63671c8b4' User entered '97.8'	System	27 Aug 2020 15:53:19
	System	27 Aug 2020 15:53:19

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:52:53', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '464cf8d1-384c-4f89-8291-e3d63671c8b4' User entered 'No (N)'	System	27 Aug 2020 15:53:19
	System	27 Aug 2020 15:53:19

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:53:15', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '464cf8d1-384c-4f89-8291-e3d63671c8b4' User entered '27 Aug 2020 11:53'	System	27 Aug 2020 15:53:19
	System	27 Aug 2020 15:53:19

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '26 Aug 2020 16:40'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 2'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:47:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:49:18', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '426f6c02-55f9-4632-a4c6-68b7b11b8959' User entered 'Yes (Y)'	System	28 Aug 2020 01:49:35
	System	28 Aug 2020 01:49:35

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:47:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:47:59', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '426f6c02-55f9-4632-a4c6-68b7b11b8959' User entered '97.8'	System	28 Aug 2020 01:49:35
	System	28 Aug 2020 01:49:35

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:49:26', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '426f6c02-55f9-4632-a4c6-68b7b11b8959'	System	28 Aug 2020 01:49:35
User entered 'No (N)'	System	28 Aug 2020 01:49:35

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:49:33', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '426f6c02-55f9-4632-a4c6-68b7b11b8959'	System	28 Aug 2020 01:49:35
User entered '27 Aug 2020 21:49'	System	28 Aug 2020 01:49:35

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 3'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:47:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-28T23:26:37', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'eed622e7-2615-43d8-9edf-7cb9a5a2f077'	System	29 Aug 2020 03:28:44
User entered 'Yes (Y)'	System	29 Aug 2020 03:28:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:47:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-28T23:25:23', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'eed622e7-2615-43d8-9edf-7cb9a5a2f077' User entered '98.7'	System	29 Aug 2020 03:28:44
	System	29 Aug 2020 03:28:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-28T23:26:14', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'eed622e7-2615-43d8-9edf-7cb9a5a2f077'	System	29 Aug 2020 03:28:44
User entered 'No (N)'	System	29 Aug 2020 03:28:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-28T23:28:40', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'eed622e7-2615-43d8-9edf-7cb9a5a2f077' User entered '28 Aug 2020 23:28'	System	29 Aug 2020 03:28:44
	System	29 Aug 2020 03:28:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 4'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:47:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-30T00:11:04', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '8f70a52f-a948-4583-89c5-538b74c222fa' User entered 'Yes (Y)'	System	30 Aug 2020 04:12:16
	System	30 Aug 2020 04:12:16

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:47:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-30T00:11:55', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '8f70a52f-a948-4583-89c5-538b74c222fa' User entered '98.7'	System	30 Aug 2020 04:12:16
	System	30 Aug 2020 04:12:16

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-30T00:12:01', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '8f70a52f-a948-4583-89c5-538b74c222fa' User entered 'No (N)'	System	30 Aug 2020 04:12:16
	System	30 Aug 2020 04:12:16

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-30T00:12:13', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '8f70a52f-a948-4583-89c5-538b74c222fa' User entered '30 Aug 2020 00:12'	System	30 Aug 2020 04:12:16
	System	30 Aug 2020 04:12:16

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 5'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:47:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-31T10:07:10', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '2797a54b-7c1e-4583-b6d8-d15d8486c8e8' User entered 'Yes (Y)'	System	31 Aug 2020 14:10:03
	System	31 Aug 2020 14:10:03

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:47:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-31T10:09:40', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '2797a54b-7c1e-4583-b6d8-d15d8486c8e8' User entered '99.8'	System	31 Aug 2020 14:10:03
	System	31 Aug 2020 14:10:03

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-31T10:09:48', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '2797a54b-7c1e-4583-b6d8-d15d8486c8e8' User entered 'No (N)'	System	31 Aug 2020 14:10:03
	System	31 Aug 2020 14:10:03

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-31T10:09:58', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '2797a54b-7c1e-4583-b6d8-d15d8486c8e8' User entered '31 Aug 2020 10:09'	System	31 Aug 2020 14:10:03
	System	31 Aug 2020 14:10:03

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 6'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:47:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:47:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:47:49

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:47:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 7'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:47:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:47:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:47:49

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:47:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:32:01', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6eb6e357-737a-4056-8168-7d8643715d4f' User entered 'None (1)'	System	26 Aug 2020 17:32:39
	System	26 Aug 2020 17:32:39

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:32:05', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6eb6e357-737a-4056-8168-7d8643715d4f' User entered 'No (N)'	System	26 Aug 2020 17:32:39
	System	26 Aug 2020 17:32:39

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:32:12', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6eb6e357-737a-4056-8168-7d8643715d4f' User entered 'No (N)'	System	26 Aug 2020 17:32:39
	System	26 Aug 2020 17:32:39

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:32:23', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6eb6e357-737a-4056-8168-7d8643715d4f' User entered 'None (1)'	System	26 Aug 2020 17:32:39
	System	26 Aug 2020 17:32:39

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:32:36', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6eb6e357-737a-4056-8168-7d8643715d4f' User entered '26 Aug 2020 13:32'	System	26 Aug 2020 17:32:39
	System	26 Aug 2020 17:32:39

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '26 Aug 2020 13:15'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '26 Aug 2020 15:45'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:56:15', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '7821d848-451d-4eef-8080-c5a1126d1daa'	System	27 Aug 2020 15:57:47
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 15:57:47

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:57:01', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '7821d848-451d-4eef-8080-c5a1126d1daa' User entered 'No (N)'	System	27 Aug 2020 15:57:47
	System	27 Aug 2020 15:57:47

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:57:35', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '7821d848-451d-4eef-8080-c5a1126d1daa' User entered 'No (N)'	System	27 Aug 2020 15:57:47
	System	27 Aug 2020 15:57:47

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:56:45', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '7821d848-451d-4eef-8080-c5a1126d1daa'	System	27 Aug 2020 15:57:47
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 15:57:47

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:57:44', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '7821d848-451d-4eef-8080-c5a1126d1daa' User entered '27 Aug 2020 11:57'	System	27 Aug 2020 15:57:47
	System	27 Aug 2020 15:57:47

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '26 Aug 2020 16:40'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 2'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:51:59', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '0e322e2d-2118-46e9-b5a5-5d0369795b24'	System	28 Aug 2020 01:52:14
User entered 'None (1)'	System	28 Aug 2020 01:52:14

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:47:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:51:23', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '0e322e2d-2118-46e9-b5a5-5d0369795b24'	System	28 Aug 2020 01:52:14
User entered 'No (N)'	System	28 Aug 2020 01:52:14

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:51:30', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '0e322e2d-2118-46e9-b5a5-5d0369795b24'	System	28 Aug 2020 01:52:14
User entered 'No (N)'	System	28 Aug 2020 01:52:14

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:51:35', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '0e322e2d-2118-46e9-b5a5-5d0369795b24'	System	28 Aug 2020 01:52:14
User entered 'None (1)'	System	28 Aug 2020 01:52:14

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:52:12', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '0e322e2d-2118-46e9-b5a5-5d0369795b24' User entered '27 Aug 2020 21:52'	System	28 Aug 2020 01:52:14
	System	28 Aug 2020 01:52:14

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 3'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:47:49

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:47:49

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 4'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:47:49

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:47:49

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 5'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:47:49

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:47:49

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 6'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:47:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:47:49

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:47:49

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 7'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:47:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:47:49

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:47:49

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:47:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:47:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:32:52', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'd8134085-8dc7-4a3b-a6dd-ccb2bd3531a8' User entered 'None (0)'	System	26 Aug 2020 17:33:36
	System	26 Aug 2020 17:33:36

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:32:57', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'd8134085-8dc7-4a3b-a6dd-ccb2bd3531a8' User entered 'None (0)'	System	26 Aug 2020 17:33:36
	System	26 Aug 2020 17:33:36

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:33:01', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'd8134085-8dc7-4a3b-a6dd-ccb2bd3531a8' User entered 'None (0)'	System	26 Aug 2020 17:33:36
	System	26 Aug 2020 17:33:36

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:33:05', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'd8134085-8dc7-4a3b-a6dd-ccb2bd3531a8' User entered 'None (0)'	System	26 Aug 2020 17:33:36
	System	26 Aug 2020 17:33:36

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:33:09', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'd8134085-8dc7-4a3b-a6dd-ccb2bd3531a8' User entered 'None (0)'	System	26 Aug 2020 17:33:36
	System	26 Aug 2020 17:33:36

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:33:12', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'd8134085-8dc7-4a3b-a6dd-ccb2bd3531a8' User entered 'None (0)'	System	26 Aug 2020 17:33:36
	System	26 Aug 2020 17:33:36

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:33:21', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'd8134085-8dc7-4a3b-a6dd-ccb2bd3531a8'	System	26 Aug 2020 17:33:36
User entered 'No (N)'	System	26 Aug 2020 17:33:36

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-26T13:33:31', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'd8134085-8dc7-4a3b-a6dd-ccb2bd3531a8' User entered '26 Aug 2020 13:33'	System	26 Aug 2020 17:33:36
	System	26 Aug 2020 17:33:36

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '26 Aug 2020 13:15'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '26 Aug 2020 15:45'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:54:20', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '73cf2311-2dde-4b32-b779-b0462117853a'	System	27 Aug 2020 15:55:56
User entered 'No interference with activity (1)'	System	27 Aug 2020 15:55:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:54:40', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '73cf2311-2dde-4b32-b779-b0462117853a'	System	27 Aug 2020 15:55:56
User entered 'No interference with activity (1)'	System	27 Aug 2020 15:55:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:54:53', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '73cf2311-2dde-4b32-b779-b0462117853a'	System	27 Aug 2020 15:55:56
User entered 'No interference with activity (1)'	System	27 Aug 2020 15:55:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:55:03', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '73cf2311-2dde-4b32-b779-b0462117853a'	System	27 Aug 2020 15:55:56
User entered 'No interference with activity (1)'	System	27 Aug 2020 15:55:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:55:15', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '73cf2311-2dde-4b32-b779-b0462117853a'	System	27 Aug 2020 15:55:56
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	27 Aug 2020 15:55:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:55:24', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '73cf2311-2dde-4b32-b779-b0462117853a'	System	27 Aug 2020 15:55:56
User entered 'No interference with activity (1)'	System	27 Aug 2020 15:55:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:55:42', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '73cf2311-2dde-4b32-b779-b0462117853a' User entered 'No (N)'	System	27 Aug 2020 15:55:56
	System	27 Aug 2020 15:55:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T11:55:51', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '73cf2311-2dde-4b32-b779-b0462117853a' User entered '27 Aug 2020 11:55'	System	27 Aug 2020 15:55:56
	System	27 Aug 2020 15:55:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '26 Aug 2020 16:40'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 2'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:50:52', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e5ede391-ab70-480d-9a3a-0005a8f25d51' User entered 'None (0)'	System	28 Aug 2020 01:51:02
	System	28 Aug 2020 01:51:02

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:49:59', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e5ede391-ab70-480d-9a3a-0005a8f25d51' User entered 'None (0)'	System	28 Aug 2020 01:51:02
	System	28 Aug 2020 01:51:02

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:50:05', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e5ede391-ab70-480d-9a3a-0005a8f25d51' User entered 'None (0)'	System	28 Aug 2020 01:51:02
	System	28 Aug 2020 01:51:02

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:50:14', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e5ede391-ab70-480d-9a3a-0005a8f25d51'	System	28 Aug 2020 01:51:02
User entered 'No interference with activity (1)'	System	28 Aug 2020 01:51:02

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:50:20', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e5ede391-ab70-480d-9a3a-0005a8f25d51' User entered 'None (0)'	System	28 Aug 2020 01:51:02
	System	28 Aug 2020 01:51:02

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:50:24', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e5ede391-ab70-480d-9a3a-0005a8f25d51' User entered 'None (0)'	System	28 Aug 2020 01:51:02
	System	28 Aug 2020 01:51:02

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:50:35', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e5ede391-ab70-480d-9a3a-0005a8f25d51' User entered 'No (N)'	System	28 Aug 2020 01:51:02
	System	28 Aug 2020 01:51:02

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-27T21:51:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e5ede391-ab70-480d-9a3a-0005a8f25d51' User entered '27 Aug 2020 21:51'	System	28 Aug 2020 01:51:02
	System	28 Aug 2020 01:51:02

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 3'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-28T23:29:20', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '64b77e24-1b00-4437-b532-18cf3dccc37'	System	29 Aug 2020 03:30:20
User entered 'No interference with activity (1)'	System	29 Aug 2020 03:30:20

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-28T23:29:33', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '64b77e24-1b00-4437-b532-18cf3dccc37' User entered 'None (0)'	System	29 Aug 2020 03:30:20
	System	29 Aug 2020 03:30:20

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-28T23:29:41', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '64b77e24-1b00-4437-b532-18cf3dccc37' User entered 'None (0)'	System	29 Aug 2020 03:30:20
	System	29 Aug 2020 03:30:20

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-28T23:29:46', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '64b77e24-1b00-4437-b532-18cf3dccc37' User entered 'None (0)'	System	29 Aug 2020 03:30:20
	System	29 Aug 2020 03:30:20

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-28T23:29:52', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '64b77e24-1b00-4437-b532-18cf3dccc37' User entered 'None (0)'	System	29 Aug 2020 03:30:20
	System	29 Aug 2020 03:30:20

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-28T23:29:57', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '64b77e24-1b00-4437-b532-18cf3dccc37' User entered 'None (0)'	System	29 Aug 2020 03:30:20
	System	29 Aug 2020 03:30:20

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-28T23:30:11', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '64b77e24-1b00-4437-b532-18cf3dccc37'	System	29 Aug 2020 03:30:20
User entered 'No (N)'	System	29 Aug 2020 03:30:20

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-28T23:30:18', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '64b77e24-1b00-4437-b532-18cf3dccc37'	System	29 Aug 2020 03:30:20
User entered '28 Aug 2020 23:30'	System	29 Aug 2020 03:30:20

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 4'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-30T00:15:08', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e1f19eb0-0d53-4da8-899c-3fc3de5d7324' User entered 'None (0)'	System	30 Aug 2020 04:16:00
	System	30 Aug 2020 04:16:00

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-30T00:15:12', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e1f19eb0-0d53-4da8-899c-3fc3de5d7324' User entered 'None (0)'	System	30 Aug 2020 04:16:00
	System	30 Aug 2020 04:16:00

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-30T00:15:18', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e1f19eb0-0d53-4da8-899c-3fc3de5d7324' User entered 'None (0)'	System	30 Aug 2020 04:16:00
	System	30 Aug 2020 04:16:00

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-30T00:15:23', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e1f19eb0-0d53-4da8-899c-3fc3de5d7324' User entered 'None (0)'	System	30 Aug 2020 04:16:00
	System	30 Aug 2020 04:16:00

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-30T00:15:28', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e1f19eb0-0d53-4da8-899c-3fc3de5d7324' User entered 'None (0)'	System	30 Aug 2020 04:16:00
	System	30 Aug 2020 04:16:00

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-30T00:15:40', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e1f19eb0-0d53-4da8-899c-3fc3de5d7324' User entered 'None (0)'	System	30 Aug 2020 04:16:00
	System	30 Aug 2020 04:16:00

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-30T00:15:50', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e1f19eb0-0d53-4da8-899c-3fc3de5d7324' User entered 'No (N)'	System	30 Aug 2020 04:16:00
	System	30 Aug 2020 04:16:00

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-30T00:15:58', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e1f19eb0-0d53-4da8-899c-3fc3de5d7324' User entered '30 Aug 2020 00:15'	System	30 Aug 2020 04:16:00
	System	30 Aug 2020 04:16:00

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 5'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-31T10:10:25', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6bf2f3da-5c5b-4d12-9606-ebe10f685e8d'	System	31 Aug 2020 14:11:46
User entered 'No interference with activity (1)'	System	31 Aug 2020 14:11:46

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-31T10:10:37', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6bf2f3da-5c5b-4d12-9606-ebe10f685e8d'	System	31 Aug 2020 14:11:46
User entered 'No interference with activity (1)'	System	31 Aug 2020 14:11:46

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-31T10:10:46', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6bf2f3da-5c5b-4d12-9606-ebe10f685e8d' User entered 'No interference with activity (1)'	System	31 Aug 2020 14:11:46
	System	31 Aug 2020 14:11:46

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-31T10:10:54', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6bf2f3da-5c5b-4d12-9606-ebe10f685e8d'	System	31 Aug 2020 14:11:46
User entered 'No interference with activity (1)'	System	31 Aug 2020 14:11:46

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-31T10:11:02', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6bf2f3da-5c5b-4d12-9606-ebe10f685e8d'	System	31 Aug 2020 14:11:46
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	31 Aug 2020 14:11:46

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-31T10:11:12', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6bf2f3da-5c5b-4d12-9606-ebe10f685e8d'	System	31 Aug 2020 14:11:46
User entered 'No interference with activity (1)'	System	31 Aug 2020 14:11:46

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-31T10:11:37', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6bf2f3da-5c5b-4d12-9606-ebe10f685e8d' User entered 'No (N)'	System	31 Aug 2020 14:11:46
	System	31 Aug 2020 14:11:46

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AEDFA32-89DD-4D1D-969F-C65C99112481)', Time: '2020-08-31T10:11:43', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '6bf2f3da-5c5b-4d12-9606-ebe10f685e8d' User entered '31 Aug 2020 10:11'	System	31 Aug 2020 14:11:46
	System	31 Aug 2020 14:11:46

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 6'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 7'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 17:21:44

US3482145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:47:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:29:56
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	02 Sep 2020 15:02:53

US3482145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 13:30:48
User entered '2 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	02 Sep 2020 15:02:53

US3482145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4)	02 Sep 2020 15:02:53

US3482145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	02 Sep 2020 15:02:53
	(b) (4)	

US3482145

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	22 Sep 2020 16:21:46

US3482145

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'I'	System	22 Sep 2020 16:21:46

US3482145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	22 Sep 2020 17:07:30

US3482145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 13:30:57
User entered '9 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Sep 2020 17:07:30

US3482145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Sarah Bechnak (b) (4)	22 Sep 2020 17:07:30

US3482145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'contact attempted on September 9,10, and 11.	(b) (4)	
Found out subject was hospitalized, SAE filled'	Sarah Bechnak (b) (4)	22 Sep 2020 17:07:30
	(b) (4)	

US3482145

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	22 Sep 2020 17:06:08

US3482145

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:29:12
User entered 'I'	System	22 Sep 2020 17:06:08

US3482145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:37:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	22 Sep 2020 17:16:01

US3482145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:37:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '16 Sep 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	22 Sep 2020 17:16:01

US3482145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:37:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Sarah Bechnak (b) (4)	22 Sep 2020 17:16:01

US3482145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:37:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'contact attempted on September 16,18,21, and 22. Unable to reach participant. Called secondary contact, no answer either.'	(b) (4) Sarah Bechnak (b) (4)	22 Sep 2020 17:16:01

US3482145

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:37:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	22 Sep 2020 17:16:12

US3482145

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:37:42
User entered 'I'	System	22 Sep 2020 17:16:12

US3482145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Per CDM: 'Was this visit performed?' is NO, but vital signs and physical examination are present. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 10:47:22
Query 'Per CDM: 'Was this visit performed?' is NO, but vital signs and physical examination are present. Please review and reconcile.' answered with 'done' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	26 Oct 2020 12:05:21
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	26 Oct 2020 12:05:06
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	26 Oct 2020 12:04:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	26 Oct 2020 12:04:20
User opened query 'Per CDM: 'Was this visit performed?' is NO, but vital signs and physical examination are present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:25:18
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Sep 2020 17:16:22

US3482145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	26 Oct 2020 12:05:06
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	22 Sep 2020 17:16:22
	(b) (4)	

US3482145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	System	26 Oct 2020 12:05:06
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	Sarah Bechnak (b) (4)	26 Oct 2020 12:05:06
User entered empty.	(b) (4)	
	System	26 Oct 2020 12:04:20
	Sarah Bechnak (b) (4)	22 Sep 2020 17:16:22
	(b) (4)	

US3482145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered 'VISIT2'	System	22 Sep 2020 17:16:22

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User accepted default value 'Pre-Dose (PREDOSE)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '23 Sep 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '10:15'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered '23 Sep 2020 10:15'	System	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 13:54:12
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:19
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	23 Sep 2020 15:35:14
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 15:35:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Sep 2020 15:35:14
User entered '96.6' F reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:14
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 15:34:37
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	23 Sep 2020 15:35:14
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	23 Sep 2020 15:34:37
	(b) (4)	

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	23 Sep 2020 15:34:37
	(b) (4)	

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 15:35:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 15:35:14
User entered '78' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	23 Sep 2020 15:35:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 15:34:37
User entered empty.	System	23 Sep 2020 15:34:37
	Sarah Bechnak (b) (4)	23 Sep 2020 15:34:37
	(b) (4)	

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered 'bpm'	System	23 Sep 2020 15:35:14
User entered empty.	System	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 15:35:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 15:35:14
User entered '20' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	23 Sep 2020 15:35:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 15:34:37
User entered empty.	System	23 Sep 2020 15:34:37
	Sarah Bechnak (b) (4)	23 Sep 2020 15:34:37
	(b) (4)	

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered 'breaths/min'	System	23 Sep 2020 15:35:14
User entered empty.	System	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 15:35:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 15:35:14
User entered '108' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	23 Sep 2020 15:35:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 15:34:37
User entered empty.	System	23 Sep 2020 15:34:37
	Sarah Bechnak (b) (4)	23 Sep 2020 15:34:37
	(b) (4)	

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered 'mmHg'	System	23 Sep 2020 15:35:14
User entered empty.	System	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 15:35:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 15:35:14
User entered '67' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	23 Sep 2020 15:35:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 15:34:37
User entered empty.	System	23 Sep 2020 15:34:37
	Sarah Bechnak (b) (4)	23 Sep 2020 15:34:37
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered 'mmHg'	System	23 Sep 2020 15:35:14
User entered empty.	System	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User accepted default value 'Post-Dose (POSTDOSE)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	23 Sep 2020 15:34:37
	(b) (4)	

US3482145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	23 Sep 2020 15:34:37

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	23 Sep 2020 15:34:37

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	23 Sep 2020 15:34:37

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:34:37

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	23 Sep 2020 15:34:37

US3482145

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:26

US3482145

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4)	
User entered '23 Sep 2020' reason for change: Data Entry Error	System	23 Sep 2020 15:35:32
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	Sarah Bechnak (b) (4)	23 Sep 2020 15:35:32
User entered empty.	(b) (4)	
	System	23 Sep 2020 15:35:26
	Sarah Bechnak (b) (4)	23 Sep 2020 15:35:26
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	23 Sep 2020 14:53:17

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Sarah Bechnak (b) (4)	17 Nov 2020 14:18:42
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4)	
	Sarah Bechnak (b) (4)	23 Sep 2020 14:53:17
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'SAE FILLED AFTER HOSPITALIZATION. SUBJECT HAS UNSTABLE MEDICAL CONDITIONS, Inclusion criteria not met.' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	17 Nov 2020 14:18:42
User entered 'SAE filled after hospitalization. Subject has unstable medical conditions.'	(b) (4)	
	Sarah Bechnak (b) (4)	23 Sep 2020 14:53:17
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	23 Sep 2020 14:53:17

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	23 Sep 2020 14:53:17

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	23 Sep 2020 14:53:17
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	23 Sep 2020 14:53:17

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 14:53:17

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	23 Sep 2020 14:53:17

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	23 Sep 2020 14:53:17

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:43

US3482145

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '23 Sep 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:43

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '10:40'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:43

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered '23 Sep 2020 10:40'	System	23 Sep 2020 15:35:43

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:47:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '23 Sep 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:56

US3482145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:47:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:56

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:47:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:56

US3482145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:47:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '10:35'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:56

US3482145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered '23 Sep 2020 10:35'	System	23 Sep 2020 15:35:56

US3482145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:47:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:56

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:47:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:56

US3482145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:47:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 15:35:56

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	23 Sep 2020 15:35:56

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Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	23 Sep 2020 15:36:00

US3482145

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered 'I'	System	23 Sep 2020 15:36:00

US3482145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	30 Sep 2020 20:28:27

US3482145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '30 Sep 2020'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	30 Sep 2020 20:28:27

US3482145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4)	30 Sep 2020 20:28:27

US3482145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	30 Sep 2020 20:28:27

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Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	30 Sep 2020 20:28:32

US3482145

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered 'I'	System	30 Sep 2020 20:28:32

US3482145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	07 Oct 2020 16:19:06

US3482145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 13:31:14
User entered '7 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	07 Oct 2020 16:19:06

US3482145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	07 Oct 2020 16:19:06

US3482145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	07 Oct 2020 16:19:06

US3482145

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	07 Oct 2020 16:19:11

US3482145

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered 'I'	System	07 Oct 2020 16:19:11

US3482145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Oct 2020 20:25:15

US3482145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered '14 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	14 Oct 2020 20:25:15
	(b) (4)	

US3482145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4)	14 Oct 2020 20:25:15

US3482145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Oct 2020 20:25:15

US3482145

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	14 Oct 2020 20:25:20

US3482145

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered 'I'	System	14 Oct 2020 20:25:20

US3482145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	29 Nov 2020 15:18:07
	(b) (4)	

US3482145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	29 Nov 2020 15:18:07
	(b) (4)	

US3482145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	29 Nov 2020 15:18:07
	(b) (4)	

US3482145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered 'VISIT3'	System	29 Nov 2020 15:18:07

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'No (N)'	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	30 Mar 2021 14:23:21

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46

US3482145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46

US3482145

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'No (N)'	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:23:32

US3482145

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:23:32

US3482145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'No (N)'	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:24:13

US3482145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:24:13

US3482145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:24:13

US3482145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered empty.	System	30 Mar 2021 14:24:13

US3482145

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:25:58
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	29 Nov 2020 15:17:25

US3482145

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered 'I'	System	29 Nov 2020 15:17:25

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 64'	System	26 Aug 2020 17:21:44

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
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US3482145

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12
Data entry locked.	System	26 Aug 2020 17:21:44
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 17:21:44

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12
Data entry locked.	System	26 Aug 2020 17:21:44
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 71'	System	26 Aug 2020 17:21:44

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
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Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:47:49

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

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Folder: Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:47:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3482145

Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

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Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12
Data entry locked.	System	26 Aug 2020 17:21:44
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 17:21:44

US3482145

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12
Data entry locked.	System	26 Aug 2020 17:21:44
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12
Data entry locked.	System	26 Aug 2020 17:21:44
User entered 'Day 78'	System	26 Aug 2020 17:21:44

US3482145

Folder: Safety Follow Up Diary (1)

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[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Folder: Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

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Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

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Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:47:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

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Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12
Data entry locked.	System	26 Aug 2020 17:21:44
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 17:21:44

US3482145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:07:12
Data entry locked.	System	26 Aug 2020 17:21:44
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 17:21:44

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2020-11-20T13:35:06', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '7729d4b5-2963-4364-8826-9129cdf4edd3'	System	20 Nov 2020 18:35:42
User entered 'No (N)'	System	20 Nov 2020 18:35:42

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2020-11-20T13:35:18', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '7729d4b5-2963-4364-8826-9129cdf4edd3'	System	20 Nov 2020 18:35:42
User entered 'No (N)'	System	20 Nov 2020 18:35:42

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2020-11-20T13:35:38', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '7729d4b5-2963-4364-8826-9129cdf4edd3' User entered '20 Nov 2020 13:35:38'	System	20 Nov 2020 18:35:42

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2020-12-04T06:48:05', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '7b828235-dd0e-47d8-ad46-e0c79dc17918'	System	04 Dec 2020 11:48:33
User entered 'No (N)'	System	04 Dec 2020 11:48:33

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2020-12-04T06:47:44', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '7b828235-dd0e-47d8-ad46-e0c79dc17918'	System	04 Dec 2020 11:48:33
User entered 'No (N)'	System	04 Dec 2020 11:48:33

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2020-12-04T06:48:30', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '7b828235-dd0e-47d8-ad46-e0c79dc17918' User entered '04 Dec 2020 06:48:30'	System	04 Dec 2020 11:48:33
	System	04 Dec 2020 11:48:33

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2020-12-26T18:44:15', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '1123776d-199c-4fa4-b63e-a681b41fcc9d' User entered 'No (N)'	System	26 Dec 2020 23:45:02
	System	26 Dec 2020 23:45:02

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2020-12-26T18:44:26', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '1123776d-199c-4fa4-b63e-a681b41fcc9d' User entered 'No (N)'	System	26 Dec 2020 23:45:02
	System	26 Dec 2020 23:45:02

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2020-12-26T18:44:59', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '1123776d-199c-4fa4-b63e-a681b41fcc9d' User entered '26 Dec 2020 18:44:59'	System	26 Dec 2020 23:45:02
	System	26 Dec 2020 23:45:02

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-01-05T06:11:56', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '93631f52-a8b7-41f1-a76e-d2af311c005d' User entered 'No (N)'	System	05 Jan 2021 11:12:22
	System	05 Jan 2021 11:12:22

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-01-05T06:12:06', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '93631f52-a8b7-41f1-a76e-d2af311c005d'	System	05 Jan 2021 11:12:22
User entered 'No (N)'	System	05 Jan 2021 11:12:22

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-01-05T06:12:18', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '93631f52-a8b7-41f1-a76e-d2af311c005d' User entered '05 Jan 2021 06:12:18'	System	05 Jan 2021 11:12:22
	System	05 Jan 2021 11:12:22

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-01-11T01:31:01', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '81b86dfe-f30e-4b1b-9ba9-ce3e5d3bc736'	System	11 Jan 2021 06:31:10
User entered 'No (N)'	System	11 Jan 2021 06:31:10

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-01-11T01:30:47', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '81b86dfe-f30e-4b1b-9ba9-ce3e5d3bc736'	System	11 Jan 2021 06:31:10
User entered 'No (N)'	System	11 Jan 2021 06:31:10

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-01-11T01:31:07', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '81b86dfe-f30e-4b1b-9ba9-ce3e5d3bc736' User entered '11 Jan 2021 01:31:07'	System	11 Jan 2021 06:31:10
	System	11 Jan 2021 06:31:10

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-01-22T00:35:04', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '8bda76bc-fe98-48c6-aa40-0ab1d377538b' User entered 'No (N)'	System	22 Jan 2021 05:35:16
	System	22 Jan 2021 05:35:16

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-01-22T00:34:52', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '8bda76bc-fe98-48c6-aa40-0ab1d377538b' User entered 'No (N)'	System	22 Jan 2021 05:35:16
	System	22 Jan 2021 05:35:16

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-01-22T00:35:12', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '8bda76bc-fe98-48c6-aa40-0ab1d377538b' User entered '22 Jan 2021 00:35:12'	System	22 Jan 2021 05:35:16
	System	22 Jan 2021 05:35:16

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-01-31T04:20:44', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '81d97a91-b750-46b7-93e5-34a360d46d27'	System	31 Jan 2021 09:21:12
User entered 'No (N)'	System	31 Jan 2021 09:21:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-01-31T04:20:55', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '81d97a91-b750-46b7-93e5-34a360d46d27'	System	31 Jan 2021 09:21:12
User entered 'No (N)'	System	31 Jan 2021 09:21:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-01-31T04:21:09', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '81d97a91-b750-46b7-93e5-34a360d46d27'	System	31 Jan 2021 09:21:12
User entered '31 Jan 2021 04:21:09'	System	31 Jan 2021 09:21:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-02-07T01:13:47', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'ec5cc224-ae30-4a4f-99af-a775135a7c66'	System	07 Feb 2021 06:14:03
User entered 'No (N)'	System	07 Feb 2021 06:14:03

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-02-07T01:13:54', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'ec5cc224-ae30-4a4f-99af-a775135a7c66'	System	07 Feb 2021 06:14:03
User entered 'No (N)'	System	07 Feb 2021 06:14:03

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-02-07T01:14:01', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'ec5cc224-ae30-4a4f-99af-a775135a7c66' User entered '07 Feb 2021 01:14:01'	System	07 Feb 2021 06:14:03
	System	07 Feb 2021 06:14:03

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-02-12T02:26:25', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'ad5c7c7b-1127-4ab0-8df4-65a42061198a' User entered 'No (N)'	System	12 Feb 2021 07:26:52
	System	12 Feb 2021 07:26:52

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-02-12T02:26:31', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'ad5c7c7b-1127-4ab0-8df4-65a42061198a' User entered 'No (N)'	System	12 Feb 2021 07:26:52
	System	12 Feb 2021 07:26:52

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-02-12T02:26:48', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'ad5c7c7b-1127-4ab0-8df4-65a42061198a' User entered '12 Feb 2021 02:26:48'	System	12 Feb 2021 07:26:52
	System	12 Feb 2021 07:26:52

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-02-23T19:40:13-05:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '8ac5e5ec-7bdd-4539-b1c7-865a31ccdff8'	System	24 Feb 2021 00:40:29
User entered 'No (N)'	System	24 Feb 2021 00:40:29

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-02-23T19:40:20-05:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '8ac5e5ec-7bdd-4539-b1c7-865a31ccdff8'	System	24 Feb 2021 00:40:29
User entered 'No (N)'	System	24 Feb 2021 00:40:29

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-02-23T19:40:26-05:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '8ac5e5ec-7bdd-4539-b1c7-865a31ccdff8'	System	24 Feb 2021 00:40:29
User entered '24 Feb 2021 00:40:26'	System	24 Feb 2021 00:40:29

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-01T03:26:40-05:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'f34e6eed-24e6-498a-8387-628c8518c446'	System	01 Mar 2021 08:27:21
User entered 'No (N)'	System	01 Mar 2021 08:27:21

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-01T03:26:50-05:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'f34e6eed-24e6-498a-8387-628c8518c446'	System	01 Mar 2021 08:27:21
User entered 'No (N)'	System	01 Mar 2021 08:27:21

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-01T03:27:16-05:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'f34e6eed-24e6-498a-8387-628c8518c446'	System	01 Mar 2021 08:27:21
User entered '01 Mar 2021 03:27:16'	System	01 Mar 2021 08:27:21

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-09T01:10:14-05:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e2219a26-9378-490d-abae-160e57a6ee89'	System	09 Mar 2021 06:10:39
User entered 'No (N)'	System	09 Mar 2021 06:10:39

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-09T01:10:24-05:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e2219a26-9378-490d-abae-160e57a6ee89'	System	09 Mar 2021 06:10:39
User entered 'No (N)'	System	09 Mar 2021 06:10:39

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-09T01:10:35-05:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: 'e2219a26-9378-490d-abae-160e57a6ee89' User entered '09 Mar 2021 01:10:35'	System	09 Mar 2021 06:10:39
	System	09 Mar 2021 06:10:39

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-16T01:05:21-04:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '78cff6e7-5487-4c73-a158-e67886faf954'	System	16 Mar 2021 05:05:58
User entered 'No (N)'	System	16 Mar 2021 05:05:58

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-16T01:05:33-04:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '78cff6e7-5487-4c73-a158-e67886faf954'	System	16 Mar 2021 05:05:58
User entered 'No (N)'	System	16 Mar 2021 05:05:58

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-16T01:05:54-04:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '78cff6e7-5487-4c73-a158-e67886faf954' User entered '16 Mar 2021 01:05:54'	System	16 Mar 2021 05:05:58
	System	16 Mar 2021 05:05:58

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-26T22:33:32-04:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '4451080f-abfb-4851-b869-5245b6d938fc' User entered 'No (N)'	System	27 Mar 2021 02:34:23
	System	27 Mar 2021 02:34:23

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-26T22:33:43-04:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '4451080f-abfb-4851-b869-5245b6d938fc' User entered 'No (N)'	System	27 Mar 2021 02:34:23
	System	27 Mar 2021 02:34:23

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-26T22:33:59-04:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '4451080f-abfb-4851-b869-5245b6d938fc' User entered '26 Mar 2021 22:33:59'	System	27 Mar 2021 02:34:23
	System	27 Mar 2021 02:34:23

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-04-02T14:44:27-04:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '04672e20-3faa-4727-93d0-7f3870f812c3'	System	02 Apr 2021 18:45:02
User entered 'No (N)'	System	02 Apr 2021 18:45:02

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-04-02T14:44:37-04:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '04672e20-3faa-4727-93d0-7f3870f812c3' User entered 'No (N)'	System	02 Apr 2021 18:45:02
	System	02 Apr 2021 18:45:02

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-04-02T14:44:56-04:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '04672e20-3faa-4727-93d0-7f3870f812c3'	System	02 Apr 2021 18:45:02
User entered '02 Apr 2021 14:44:56'	System	02 Apr 2021 18:45:02

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:07:12

US3482145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:47:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:07:12
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:07:12

US3482145

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:47:49

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-09T07:03:00-05:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '34f078e3-0743-4ef1-9722-6d0b75e86913'	System	09 Mar 2021 12:03:33
User entered 'No (N)'	System	09 Mar 2021 12:03:33

US3482145

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:47:49

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A45CE23-193D-4C54-AC7A-585ED5D95B2B)', Time: '2021-03-09T07:03:30-05:00', User OID: 'PatientReportedOutcome (US3482145)', ODM File OID: '34f078e3-0743-4ef1-9722-6d0b75e86913' User entered '09 Mar 2021 07:03:30'	System	09 Mar 2021 12:03:33
	System	09 Mar 2021 12:03:33

US3482145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	04 Jan 2021 16:23:03
User entered 'Yes (Y)'	System	04 Jan 2021 16:21:10
	(b) (4), (b) (6)	04 Jan 2021 16:21:10

US3482145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Jan 2021 16:23:03
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 16:21:10

US3482145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 16:21:10

US3482145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	04 Jan 2021 16:23:03
Please review and reconcile.' (Site from System).		
User entered 'Protocol Deviation completed, subject paid phone bill to allow future communication' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Jan 2021 16:23:03
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	04 Jan 2021 16:21:10
Please review and reconcile.' (Site from System).		
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 16:21:10

US3482145

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 16:23:11

US3482145

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:46
User entered 'I'	System	04 Jan 2021 16:23:11

US3482145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 16:23:25

US3482145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 16:23:25

US3482145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 16:23:25

US3482145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 16:23:25

US3482145

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:25
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 16:23:29

US3482145

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:25
User entered 'I'	System	04 Jan 2021 16:23:29

US3482145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	03 Feb 2021 18:47:32

US3482145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '22 Jan 2021'	(b) (4) Sarah Bechnak (b) (4)	03 Feb 2021 18:47:32

US3482145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4)	03 Feb 2021 18:47:32

US3482145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	03 Feb 2021 18:47:32

US3482145

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	03 Feb 2021 18:47:42

US3482145

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User entered 'I'	System	03 Feb 2021 18:47:42

US3482145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Mar 2021 19:28:53

US3482145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '19 Feb 2021' reason for change: Data Entry Error	System	19 Mar 2021 19:28:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Sarah Bechnak (b) (4)	19 Mar 2021 19:28:59
User entered '29 Feb 2021' (non-conformant).	(b) (4)	
	System	19 Mar 2021 19:28:53
	Sarah Bechnak (b) (4)	19 Mar 2021 19:28:53
	(b) (4)	

US3482145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4)	19 Mar 2021 19:28:53

US3482145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Mar 2021 19:28:53

US3482145

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Mar 2021 19:28:41

US3482145

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User entered 'I'	System	19 Mar 2021 19:28:41

US3482145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Per CDM: Please complete Vital Signs page under Visit 4 folder. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 06:49:59
Query 'Per CDM: Please complete Vital Signs page under Visit 4 folder. Thank you.' answered with 'done' (Site from DM).	Mari Hart (b) (4) (b) (4)	30 Mar 2021 14:23:03
User opened query 'Per CDM: Please complete Vital Signs page under Visit 4 folder. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:36:08
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	22 Mar 2021 13:38:04

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Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '22 Mar 2021'	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:38:04
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Clinic (Clinic)'	Sarah Bechnak (b) (4)	22 Mar 2021 13:38:04

US3482145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User entered 'VISIT4'	System	22 Mar 2021 13:38:04

US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'No (N)'	Mari Hart (b) (4)	30 Mar 2021 14:22:51

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 14:22:51

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	Mari Hart (b) (4)	30 Mar 2021 14:22:51

US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User entered empty.	System	30 Mar 2021 14:22:51

US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	Mari Hart (b) (4)	30 Mar 2021 14:22:51

US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	Mari Hart (b) (4)	30 Mar 2021 14:22:51

US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	Mari Hart (b) (4)	30 Mar 2021 14:22:51

US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	Mari Hart (b) (4)	30 Mar 2021 14:22:51

US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User entered empty.	System	30 Mar 2021 14:22:51

US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	Mari Hart (b) (4)	30 Mar 2021 14:22:51

US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User entered empty.	System	30 Mar 2021 14:22:51

US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	Mari Hart (b) (4)	30 Mar 2021 14:22:51

US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User entered empty.	System	30 Mar 2021 14:22:51

US3482145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	Mari Hart (b) (4)	30 Mar 2021 14:22:51

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User entered empty.	System	30 Mar 2021 14:22:51

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56

US3482145

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:38:14

US3482145

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	22 Mar 2021 13:38:14
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:38:35

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '22 Mar 2021'	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:38:35
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '09:20'	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:38:35
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User entered '22 Mar 2021 09:20'	System	22 Mar 2021 13:38:35

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Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:38:44

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Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:31:56
User entered 'I'	System	22 Mar 2021 13:38:44

US3482145

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

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	14 Jan 2021 20:38:48

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

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	23 Feb 2021 16:46:39
User entered '22 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	29 Jan 2021 13:59:03
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	29 Jan 2021 13:55:26
User entered '22 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	22 Jan 2021 17:39:37
User entered '14 Jan 2021'	(b) (4)	
	Sarah Bechnak (b) (4)	14 Jan 2021 20:38:48
	(b) (4)	

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

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[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 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Clinic (Clinic)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 20:38:48

US3482145

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

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 20:38:48

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

Form: Unblinding

Generated On: 09 Jun 2021 17:47:49

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '14 Jan 2021'	(b) (4) Sarah Bechnak (b) (4)	14 Jan 2021 20:39:07

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

Form: Unblinding

Generated On: 09 Jun 2021 17:47:49

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:14:06
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	09 Apr 2021 14:24:04
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 13:59:44

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

Form: Unblinding

Generated On: 09 Jun 2021 17:47:49

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Jan 2021 03:03:10
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'subject only received one dose' (Site from System).	Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 20:39:25
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	14 Jan 2021 20:39:07
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 20:39:07

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

Form: Unblinding

Generated On: 09 Jun 2021 17:47:49

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:14:06
User closed query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 10:21:57
Query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	09 Apr 2021 14:24:47
User entered 'Amendment 6 or later (Amendment 6 or later)'	Sarah Bechnak (b) (4) (b) (4)	09 Apr 2021 14:24:04
User opened query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 06:40:26
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:59:44

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

Form: Unblinding

Generated On: 09 Jun 2021 17:47:49

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '14 Jan 2021'	(b) (4) Sarah Bechnak (b) (4)	14 Jan 2021 20:39:07

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

Form: Unblinding

Generated On: 09 Jun 2021 17:47:49

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Placebo (Placebo)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 20:39:07

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

Form: Unblinding

Generated On: 09 Jun 2021 17:47:49

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 08:27:33
User entered 'Placebo (Placebo)'	Sarah Bechnak (b) (4)	14 Jan 2021 20:39:07
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 17:47:49

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Not Administered (NA)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	22 Jan 2021 17:37:18
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	14 Jan 2021 20:39:07
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 17:47:49

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	22 Jan 2021 17:37:05
User entered 'No (N)'	(b) (4)	
	Sarah Bechnak (b) (4)	14 Jan 2021 20:39:07
	(b) (4)	

US3482145

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

Form: Unblinding

Generated On: 09 Jun 2021 17:47:49

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'I'	System	22 Jan 2021 17:37:18
User entered empty.	System	14 Jan 2021 20:39:07

US3482145

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

Form: Unblinding

Generated On: 09 Jun 2021 17:47:49

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'I'	System	22 Jan 2021 17:37:18
User entered empty.	System	14 Jan 2021 20:39:07

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29

US3482145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered empty.	System	22 Jan 2021 17:57:29
DataPoint set to visible.	System	22 Jan 2021 17:37:18

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered empty.	System	22 Jan 2021 17:57:29
DataPoint set to visible.	System	22 Jan 2021 17:37:18

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User accepted default value 'Pre-Dose (PREDOSE)'	Sarah Bechnak (b) (4) (b) (4)	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	29 Jan 2021 13:59:03
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Jan 2021 13:55:26
User entered '22 Jan 2021'	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '12:06'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered '22 Jan 2021 12:06'	System	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 17:57:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Jan 2021 17:57:56
User entered '97.6' F reason for change: Data Entry Error	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:56
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 17:57:29
User entered empty.	System	22 Jan 2021 17:57:29
	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:56
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	22 Jan 2021 17:57:56
data change (Site from System).		22 Jan 2021 17:57:56
User entered '86' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:56
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Jan 2021 17:57:29
User entered empty.	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered 'bpm'	System	22 Jan 2021 17:57:56
User entered empty.	System	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	22 Jan 2021 17:57:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Jan 2021 17:57:56
User entered '16' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:56
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	22 Jan 2021 17:57:29
User entered empty.	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered 'breaths/min'	System	22 Jan 2021 17:57:56
User entered empty.	System	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 17:57:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Jan 2021 17:57:56
User entered '125' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:56
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 17:57:29
User entered empty.	System	22 Jan 2021 17:57:29
	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered 'mmHg'	System	22 Jan 2021 17:57:56
User entered empty.	System	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 17:57:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Jan 2021 17:57:56
User entered '77' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:56
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 17:57:29
User entered empty.	System	22 Jan 2021 17:57:29
	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

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Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered 'mmHg'	System	22 Jan 2021 17:57:56
User entered empty.	System	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered missing code ND - Not Done.	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:47:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered empty.	System	22 Jan 2021 17:57:29
DataPoint set to visible.	System	22 Jan 2021 17:37:18

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User accepted default value 'Post-Dose (POSTDOSE)'	Sarah Bechnak (b) (4) (b) (4)	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	29 Jan 2021 13:59:03
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Jan 2021 13:55:26
User entered '22 Jan 2021'	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '13:05'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered '22 Jan 2021 13:05'	System	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 18:14:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Jan 2021 18:14:25
User entered '97.7' F reason for change: Data Entry Error	Sarah Bechnak (b) (4)	22 Jan 2021 18:14:25
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 17:57:29
User entered empty.	System	22 Jan 2021 17:57:29
	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	22 Jan 2021 18:14:25
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 18:14:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Jan 2021 18:14:25
User entered '58' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	22 Jan 2021 18:14:25
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 17:57:29
User entered empty.	System	22 Jan 2021 17:57:29
	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered 'bpm'	System	22 Jan 2021 18:14:25
User entered empty.	System	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 18:14:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Jan 2021 18:14:25
User entered '16' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	22 Jan 2021 18:14:25
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 17:57:29
User entered empty.	System	22 Jan 2021 17:57:29
	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered 'breaths/min'	System	22 Jan 2021 18:14:25
User entered empty.	System	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 18:14:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Jan 2021 18:14:25
User entered '118' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	22 Jan 2021 18:14:25
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Jan 2021 17:57:29
User entered empty.	System	22 Jan 2021 17:57:29
	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered 'mmHg'	System	22 Jan 2021 18:14:25
User entered empty.	System	22 Jan 2021 17:57:29

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	22 Jan 2021 18:14:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Jan 2021 18:14:25
User entered '62' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	22 Jan 2021 18:14:25
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	22 Jan 2021 17:57:29
User entered empty.	Sarah Bechnak (b) (4)	22 Jan 2021 17:57:29
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered 'mmHg'	System	22 Jan 2021 18:14:25
User entered empty.	System	22 Jan 2021 17:57:29

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:39:15

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	29 Jan 2021 13:59:03
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Jan 2021 13:55:26
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Jan 2021 17:39:37
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Jan 2021 17:39:15
User entered '22 Jan 2021'	Sarah Bechnak (b) (4)	22 Jan 2021 17:39:15
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:37:54

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

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:37:54
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	22 Jan 2021 17:37:54

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

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'mRNA-1273'	System	22 Jan 2021 17:37:54
DataPoint set to visible.	System	22 Jan 2021 17:37:18

US3482145

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

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:30:46
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'treatment date is not on decision visit. OL-D1 is not on the same day as decision visit.' (Site from System).	Sarah Bechnak (b) (4) (b) (4)	22 Jan 2021 17:39:04
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	22 Jan 2021 17:37:54
User entered '22 Jan 2021'	Sarah Bechnak (b) (4) (b) (4)	22 Jan 2021 17:37:54

US3482145

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

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '12:35'	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:37:54

US3482145

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

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered '22 Jan 2021 12:35'	System	22 Jan 2021 17:37:54

US3482145

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

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	22 Jan 2021 17:37:54

US3482145

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

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'ONCE'	System	22 Jan 2021 17:37:54

US3482145

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

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 17:37:54

US3482145

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	14 Jan 2021 20:39:47

US3482145

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'The Collection Date is prior to the System Participant Decision Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	23 Feb 2021 16:46:39
Amendment Manager: User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	17 Feb 2021 01:28:12
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Feb 2021 10:37:16
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered with 'subject was unblinded on jan 14 but did not meet dosing criteria. So subject received vaccine on 22nd of jan.' (Site from System).	Sarah Bechnak (b) (4)	29 Jan 2021 14:00:05
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	29 Jan 2021 13:59:03
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Jan 2021 13:55:26
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	29 Jan 2021 13:55:26
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Jan 2021 17:39:37
User entered '14 Jan 2021'	Sarah Bechnak (b) (4)	14 Jan 2021 20:39:47
	(b) (4)	

US3482145

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '14:45'	(b) (4) Sarah Bechnak (b) (4)	14 Jan 2021 20:39:47

US3482145

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered '14 Jan 2021 14:45'	System	14 Jan 2021 20:39:47

US3482145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:47:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	14 Jan 2021 20:39:59

US3482145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:47:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '14 Jan 2021'	(b) (4) Sarah Bechnak (b) (4)	14 Jan 2021 20:39:59

US3482145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:47:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '15:00'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	14 Jan 2021 20:39:59

US3482145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered '14 Jan 2021 15:00'	System	14 Jan 2021 20:39:59

US3482145

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

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	22 Jan 2021 17:39:41

US3482145

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

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'I'	System	22 Jan 2021 17:39:41

US3482145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	29 Jan 2021 17:30:30

US3482145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '29 Jan 2021'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	29 Jan 2021 17:30:30

US3482145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	29 Jan 2021 17:30:30

US3482145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	29 Jan 2021 17:30:30

US3482145

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	29 Jan 2021 17:30:36
	(b) (4)	

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered 'I'	System	29 Jan 2021 17:30:36

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered '1'	System	29 Jan 2021 17:30:36
DataPoint set to visible.	System	29 Jan 2021 17:30:36

US3482145

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Feb 2021 20:06:49

US3482145

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '19 Feb 2021'	(b) (4) Sarah Bechnak (b) (4)	19 Feb 2021 20:06:49
	(b) (4)	

US3482145

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Clinic (Clinic)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:06:49

US3482145

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'OLD29'	System	19 Feb 2021 20:06:49

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User accepted default value 'Pre-Dose (PREDOSE)'	Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '19 Feb 2021'	(b) (4) Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44
	(b) (4)	

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '14:21'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered '19 Feb 2021 14:21'	System	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '97.7' F	(b) (4) Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Oral (Oral)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '57'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'bpm'	System	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '16'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'breaths/min'	System	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '111'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'mmHg'	System	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '61'	(b) (4) Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:47:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'mmHg'	System	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User accepted default value 'Post-Dose (POSTDOSE)'	Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 21:16:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	19 Feb 2021 21:16:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	19 Feb 2021 20:17:44
	Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44
	(b) (4)	

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '19 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 21:16:02
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '15:20' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 21:16:02
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered '19 Feb 2021 15:20'	System	19 Feb 2021 21:16:02
User entered empty.	System	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '97.5' F reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 21:16:02
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44
	(b) (4)	

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 21:16:02
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:17:44

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '51' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 21:16:02
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'bpm'	System	19 Feb 2021 21:16:02
User entered empty.	System	19 Feb 2021 20:17:44

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 21:16:02
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'breaths/min'	System	19 Feb 2021 21:16:02
User entered empty.	System	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '119' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 21:16:02
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'mmHg'	System	19 Feb 2021 21:16:02
User entered empty.	System	19 Feb 2021 20:17:44

US3482145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '68' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 21:16:02
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	19 Feb 2021 20:17:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:47:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'mmHg'	System	19 Feb 2021 21:16:02
User entered empty.	System	19 Feb 2021 20:17:44

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Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Feb 2021 20:17:49

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Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '19 Feb 2021'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:17:49

US3482145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:18:24

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	19 Feb 2021 20:18:24
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:18:24

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'mRNA-1273'	System	19 Feb 2021 20:18:24
DataPoint set to visible.	System	29 Jan 2021 17:30:36

US3482145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '19 Feb 2021'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:18:24

US3482145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '14:50'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:18:24

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered '19 Feb 2021 14:50'	System	19 Feb 2021 20:18:24

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 20:18:24

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'ONCE'	System	19 Feb 2021 20:18:24

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:47:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 20:18:24

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	19 Feb 2021 20:18:28

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'I'	System	19 Feb 2021 20:18:28

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Feb 2021 17:44:57

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '26 Feb 2021'	(b) (4) Sarah Bechnak (b) (4)	26 Feb 2021 17:44:57
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Feb 2021 17:44:57

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:47:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Feb 2021 17:44:57

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	26 Feb 2021 17:44:47

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:47:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:34
User entered 'I'	System	26 Feb 2021 17:44:47

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User closed query 'Per CDM: Visit 4 and Visit OL-D57 are both dated 22Mar2021, however, Physical examination and Immunogenicity assessment eCRF are not completed on this form and at Visit 4, data yes/no is present in these eCRF pages. If the visits occurred on the same day, then the examination data and sample collection should be entered at both visits per sponsor. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:01:08
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
Query 'Per CDM: Visit 4 and Visit OL-D57 are both dated 22Mar2021, however, Physical examination and Immunogenicity assessment eCRF are not completed on this form and at Visit 4, data yes/no is present in these eCRF pages. If the visits occurred on the same day, then the examination data and sample collection should be entered at both visits per sponsor. Please review and update as appropriate. ' answered with 'Query previously resolved.' (Site from DM).	(b) (4) Mari Hart (b) (4)	01 Apr 2021 20:37:06
User opened query 'Per CDM: Visit 4 and Visit OL-D57 are both dated 22Mar2021, however, Physical examination and Immunogenicity assessment eCRF are not completed on this form and at Visit 4, data yes/no is present in these eCRF pages. If the visits occurred on the same day, then the examination data and sample collection should be entered at both visits per sponsor. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:45:57
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	22 Mar 2021 13:39:20

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '22 Mar 2021'	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:39:20
	(b) (4)	

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[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 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Clinic (Clinic)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	22 Mar 2021 13:39:20

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:47:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered 'OLD57'	System	22 Mar 2021 13:39:20

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	22 Mar 2021 13:39:42

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:39:42
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	22 Mar 2021 13:39:42

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered empty.	System	22 Mar 2021 13:39:42

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:39:42
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:39:42
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:39:42
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:39:42
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered empty.	System	22 Mar 2021 13:39:42

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:39:42
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered empty.	System	22 Mar 2021 13:39:42

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:39:42
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered empty.	System	22 Mar 2021 13:39:42

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	22 Mar 2021 13:39:42
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered empty.	System	22 Mar 2021 13:39:42

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:47:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	01 Apr 2021 17:20:23

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:47:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered empty.	(b) (4) Michelle Wiles (b) (4)	01 Apr 2021 17:20:23

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	01 Apr 2021 17:20:18

US3482145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '22 Mar 2021'	(b) (4) Michelle Wiles (b) (4)	01 Apr 2021 17:20:18

US3482145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '09:20'	(b) (4) Michelle Wiles (b) (4)	01 Apr 2021 17:20:18

US3482145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:41:33
User entered '22 Mar 2021 09:20'	System	01 Apr 2021 17:20:18

US3482145

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query 'Per CDM: Only one (the primary) AE should be recorded as IP Withdrawn. Please review the two AEs recorded and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 13:19:57
Query 'Per CDM: Only one (the primary) AE should be recorded as IP Withdrawn. Please review the two AEs recorded and update accordingly. ' answered with 'done' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:19:03
User opened query 'Per CDM: Only one (the primary) AE should be recorded as IP Withdrawn. Please review the two AEs recorded and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 18:14:37
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:20
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 20:26:06

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 21:09:43
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:10:58
User entered	System	12 Sep 2020 21:10:38
'USA-US106-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	12 Sep 2020 21:10:38

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Streptococcal sepsis, LLT: Streptococcal sepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 12:49:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 12:49:46
Data point term sent to Coder	System	11 Sep 2020 22:35:49
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 22:35:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 22:35:10
User entered 'Sepsis related to streptococcus Bacteremia' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:35:10
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 22:12:22
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:17:34
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 14:00:51
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 14:00:51
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered '2 Sep 2020'	Sarah Bechnak (b) (4)	11 Sep 2020 22:12:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Sep 2020 22:24:59
User entered empty; reason for change Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:24:59
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	11 Sep 2020 22:12:22
User entered '13:04'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:24:59
User entered '2 Sep 2020 13:04'	System	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:04:37
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	22 Sep 2020 16:29:32
DataPoint Un-verified.	Sarah Bechnak (b) (4) (b) (4)	22 Sep 2020 16:29:32
User entered 'No (N)' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Sep 2020 16:29:32
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	22 Sep 2020 16:24:49
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Sep 2020 16:46:20
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	23 Sep 2020 16:46:20
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Sep 2020 16:45:50
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 14:53:37
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Sep 2020 16:29:32
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	22 Sep 2020 16:29:32
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'done' (Site from Safety).	Sarah Bechnak (b) (4) (b) (4)	22 Sep 2020 16:25:10
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Sep 2020 16:24:49
DataPoint Un-verified.	Sarah Bechnak (b) (4) (b) (4)	22 Sep 2020 16:24:49
User entered '13 Sep 2020' reason for change: New Information	Sarah Bechnak (b) (4) (b) (4)	22 Sep 2020 16:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	21 Sep 2020 15:04:07
	(b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered empty.	Sarah Bechnak (b) (4)	11 Sep 2020 22:12:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:14:46
	(b) (4), (b) (6)	24 Nov 2020 22:02:41
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'updated' (Site from Safety). DataPoint Un-verified.	Michele McCullough (b) (4)	24 Nov 2020 21:35:52
	Michele McCullough (b) (4)	24 Nov 2020 21:35:46
User entered 'Grade 4 (Grade 4)' reason for change: Per Query Resolution	Michele McCullough (b) (4)	24 Nov 2020 21:35:46
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:07:33
	(b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:29:55
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	14 Sep 2020 13:29:55
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	11 Sep 2020 22:12:22
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered '2 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered '13 Sep 2020' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	14 Sep 2020 13:29:55
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:59:58
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).	System	14 Sep 2020 13:59:58
User entered '3' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	14 Sep 2020 13:59:58
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4) System	11 Sep 2020 22:12:22
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

US3482145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:27:51
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	23 Sep 2020 17:39:16
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'Not Related (NOT RELATED)'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'Not Related (NOT RELATED)'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query 'Per MM, please confirm the action taken with IP, as the subject did not receive the second dose after the AE outcome is recovered.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 04:42:11
Query 'Per MM, please confirm the action taken with IP, as the subject did not receive the second dose after the AE outcome is recovered.' answered with 'IP withheld due to participant not having a stable condition. It was not withheld directly after the occurrence of SAE.' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	22 Dec 2020 14:40:37
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		22 Dec 2020 14:37:21
Query 'Action Taken with Investigational Product is System Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).		22 Dec 2020 14:37:21
User entered 'None (NONE)' reason for change: Per Query Resolution	Sarah Bechnak (b) (4) (b) (4)	22 Dec 2020 14:37:21
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	22 Dec 2020 14:37:02
DataPoint Un-verified.	Sarah Bechnak (b) (4) (b) (4)	22 Dec 2020 14:37:02
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Sarah Bechnak (b) (4) (b) (4)	22 Dec 2020 14:37:02
User opened query 'Per MM, please confirm the action taken with IP, as the subject did not receive the second dose after the AE outcome is recovered.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 18:27:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:17:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		09 Nov 2020 21:10:09
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	09 Nov 2020 21:10:09
DataPoint Un-verified.	Sarah Bechnak (b) (4)	09 Nov 2020 21:10:09
User entered 'None (NONE)' reason for change: New Information	Sarah Bechnak (b) (4)	09 Nov 2020 21:10:09
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	09 Nov 2020 21:06:42
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:04:51
DataPoint Un-verified.	Sarah Bechnak (b) (4)	23 Sep 2020 17:39:16
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Sarah Bechnak (b) (4)	23 Sep 2020 17:39:16
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'None (NONE)'	Sarah Bechnak (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:04:55
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:26:21
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'done' (Site from Safety).	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 16:47:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 16:46:20
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 16:45:50
Data Entry Error		
DataPoint Un-verified.	Sarah Bechnak (b) (4) (b) (4)	22 Sep 2020 16:29:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Sarah Bechnak (b) (4) (b) (4)	22 Sep 2020 16:29:32
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:04:46
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Form: Adverse Events (1)

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query 'Per DM CLR: SAE Narrative = LEVOFLOXACIN (COURSE DONE ON SEP 16). However, in CM eCRF this is noted as ongoing. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 06:27:09
User closed query 'Per DM CLR: SAE Narrative = WBC COUNT: 13.L 10E3/MCL LACTIC ACID: 3.6 MMOL/L BNP: <4700 PG/ML. However, this is not recorded in the ConProc eCRF (i.e., Blood Work Up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:25:39
User closed query 'Per DM CLR: SAE Narrative = NEGATIVE URINE CULTURE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:25:35
User closed query 'Per DM CLR: SAE Narrative = BLOOD CULTURE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:25:33
Query 'Per DM CLR: SAE Narrative = NEGATIVE URINE CULTURE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED CON PROC' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:07:30
Query 'Per DM CLR: SAE Narrative = BLOOD CULTURE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED CON ROC' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:07:22
Query 'Per DM CLR: SAE Narrative = WBC COUNT: 13.L 10E3/MCL LACTIC ACID: 3.6 MMOL/L BNP: <4700 PG/ML. However, this is not recorded in the ConProc eCRF (i.e., Blood Work Up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED CON pROC' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:07:14

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = LEVOFLOXACIN (COURSE DONE ON SEP 16). However, in CM eCRF this is noted as ongoing. Please review and reconcile data as appropriate.'	Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:03:50
answered with 'UPDATED' (Site from DM). User opened query 'Per DM CLR: SAE Narrative = LEVOFLOXACIN (COURSE DONE ON SEP 16). However, in CM eCRF this is noted as ongoing. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:51:08
User opened query 'Per DM CLR: SAE Narrative = BLOOD CULTURE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:50:54
User opened query 'Per DM CLR: SAE Narrative = NEGATIVE URINE CULTURE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:50:44
User opened query 'Per DM CLR: SAE Narrative = WBC COUNT: 13.L 10E3/MCL LACTIC ACID: 3.6 MMOL/L BNP: <4700 PG/ML. However, this is not recorded in the ConProc eCRF (i.e., Blood Work Up). Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:50:30
User closed query 'Per DM CLR: Narrative contains a procedure. Please make sure that all procedures are recorded in the Con Proc eCRF. Update and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:49:02
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:04:58
Query 'Per DM CLR: Narrative contains a procedure. Please make sure that all procedures are recorded in the Con Proc eCRF. Update and reconcile as appropriate.'	Sarah Bechnak (b) (4) (b) (4)	21 Oct 2020 20:13:40
answered with 'done' (Site from DM). User opened query 'Per DM CLR: Narrative contains a procedure. Please make sure that all procedures are recorded in the Con Proc eCRF. Update and reconcile as appropriate.'	(b) (4), (b) (6)	19 Oct 2020 02:21:54

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory (CRP, WBC, serum lactate, ABG, BNP, etc) and diagnostic test results (urine/sputum culture, chest x-ray, echocardiogram, etc). Please include units and reference ranges when applicable. ' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:26:18
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)	23 Sep 2020 17:26:16
User closed query 'PV Query: Please confirm if levofloxacin and ceftriaxone were treatments meds for the event of sepsis related to Streptococcus bacteremia. ' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:26:13
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:26:10
User closed query 'PV Query: It was reported that the subject was admitted to the emergency department for acute cardiac heart failure exacerbation. Please assess whether it meets criteria for separate SAE reporting. If yes, please report accordingly. If no, please explain. ' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:26:07
User closed query 'PV Query: Please provide additional information regarding the course of the event, including physical exam results and vitals. ' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:26:05
User closed query 'PV Query: Please clarify if the subject had sepsis prior to receiving blinded study vaccine. If not, please delete Sepsis due to beta hemolytic streptococcus bacteremia reported in medical history. ' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:26:02
User closed query 'PV Query: What was the etiology of the sepsis? Please capture the etiology of the sepsis as an AE or SAE, as appropriate. ' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:25:59

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: It was reported that the subject was admitted to the emergency department for acute cardiac heart failure exacerbation. Please assess whether it meets criteria for separate SAE reporting. If yes, please report accordingly. If no, please explain. ' answered with 'okay.' (Site from Safety).	Sarah Bechnak (b) (4)	23 Sep 2020 17:21:06
Query 'PV Query: Please provide any relevant laboratory (CRP, WBC, serum lactate, ABG, BNP, etc) and diagnostic test results (urine/sputum culture, chest x-ray, echocardiogram, etc). Please include units and reference ranges when applicable. ' answered with 'done' (Site from Safety).	Sarah Bechnak (b) (4)	23 Sep 2020 17:12:56
Query 'PV Query: Please provide additional information regarding the course of the event, including physical exam results and vitals. ' answered with 'done' (Site from Safety).	Sarah Bechnak (b) (4)	23 Sep 2020 17:12:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT, WITH A PAST MEDICAL HISTORY SIGNIFICANT FOR CHRONIC SYSTOLIC HEART FAILURE WITH EJECTION FRACTION OF 25% WAS ADMITTED TO THE EMERGENCY DEPARTMENT ON 09/02/2020 FOR ALTERED MENTAL STATUS, BACTEREMIA, AND ACUTE CARDIAC HEART FAILURE EXACERBATION. PATIENT PRESENTED WITH: -WBC COUNT: 13.L 10E3/MCL LACTIC ACID: 3.6 MMOL/L BNP: <4700 PG/ML COVID BY PCR ON 09/02/2020: NEGATIVE URINE CULTURE: POSITIVE <10,000 CFU/ML EJECTION FRACTION ON ECHOCARDIOGRAM: 25%-30% BLOOD CULTURE: POSITIVE FOR BETA HEMOLYTIC STREPTOCOCCUS GROUP C. SUBJECT TREATED WITH CEFTRIAXONE THEN SHIFTED TO LEVOFLOXACIN (COURSE DONE ON SEP 16). VITALS ON ADMISSION: T: 37.8° ORAL. BP: 105/72 MMHG, HR: 75 BPM, SPO2: 100%. Physical exam on admission to ED: HEENT: normocephalic, atraumatic, pupils equally round and reactive to light, no JVD, no lymphadenopathy. Lungs: Clear to auscultation bilaterally. CVS: irregular rate and rhythm, no murmurs or rubs. abd: NABS, soft, nontender, non distended. EXT: no clubbing, no cyanosis, +2 edema of lower extremities bilaterally. Neuro: alert and oriented to person, place, and situation. Lethargic but arousable, no focal neurologic deficits.' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:12:28
Query 'PV Query: Please clarify if the subject had sepsis prior to receiving blinded study vaccine. If not, please delete Sepsis due to beta hemolytic streptococcus bacteremia reported in medical history. ' answered with 'done' (Site from Safety).	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 16:48:04
Query 'PV Query: What was the etiology of the sepsis? Please capture the etiology of the sepsis as an AE or SAE, as appropriate. ' answered with 'done' (Site from Safety).	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 16:44:06

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'DONE' (Site from Safety).	Sarah Bechnak (b) (4)	23 Sep 2020 16:43:33
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'DONE' (Site from Safety).	Sarah Bechnak (b) (4)	23 Sep 2020 16:43:29
DataPoint Un-verified.	Sarah Bechnak (b) (4)	23 Sep 2020 16:43:01
User entered 'SUBJECT, WITH A PAST MEDICAL HISTORY SIGNIFICANT FOR CHRONIC SYSTOLIC HEART FAILURE WITH EJECTION FRACTION OF 25% WAS ADMITTED TO THE EMERGENCY DEPARTMENT ON 09/02/2020 FOR ALTERED MENTAL STATUS, BACTEREMIA, AND ACUTE CARDIAC HEART FAILURE EXACERBATION. PATIENT PRESENTED WITH: -WBC COUNT: 13.1 10E3/mcl Lactic acid: 3.6 mmol/L BNP: <4700 pg/ml COVID by PCR on 09/02/2020: Negative Urine culture: Positive <10,000 cfu/ml Ejection fraction on Echocardiogram: 25%-30% Blood Culture: Positive for Beta Hemolytic Streptococcus group C. Subject treated with ceftriaxone then shifted to Levofloxacin (Course done on Sep 16). Vitals on admission: T: 37.8° oral. BP: 105/72 mmHg, HR: 75 BPM, SPO2: 100%.' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	23 Sep 2020 16:43:01
Query 'PV Query: Please confirm if levofloxacin and ceftriaxone were treatments meds for the event of sepsis related to Streptococcus bacteremia. ' answered with 'yes. Levofloxacin and ceftriaxone were treatment meds for sepsis' (Site from Safety).	Sarah Bechnak (b) (4)	23 Sep 2020 15:56:23

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: What was the etiology of the sepsis? Please capture the etiology of the sepsis as an AE or SAE, as appropriate. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:06:46
User opened query 'PV Query: Please clarify if the subject had sepsis prior to receiving blinded study vaccine. If not, please delete Sepsis due to beta hemolytic streptococcus bacteremia reported in medical history. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:06:32
User opened query 'PV Query: Please provide additional information regarding the course of the event, including physical exam results and vitals. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:06:02
User opened query 'PV Query: It was reported that the subject was admitted to the emergency department for acute cardiac heart failure exacerbation. Please assess whether it meets criteria for separate SAE reporting. If yes, please report accordingly. If no, please explain. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:05:48
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:05:29
User opened query 'PV Query: Please confirm if levofloxacin and ceftriaxone were treatments meds for the event of sepsis related to Streptococcus bacteremia. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:05:16
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 Sep 2020 15:05:01

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory (CRP, WBC, serum lactate, ABG, BNP, etc) and diagnostic test results (urine/sputum culture, chest x-ray, echocardiogram, etc). Please include units and reference ranges when applicable. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	21 Sep 2020 15:04:32
	(b) (4), (b) (6)	18 Sep 2020 21:09:43
User entered 'Subject, with a past medical history significant for chronic systolic heart failure with Ejection fraction of 25% was admitted to the Emergency Department on 09/02/2020 for altered mental status, bacteremia, and acute cardiac heart failure exacerbation. Patient presented' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	11 Sep 2020 22:35:10
User entered 'Subject'	Sarah Bechnak (b) (4)	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 22:12:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:15:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:38
User entered	(b) (4), (b) (6)	24 Sep 2020 02:04:34
'USA-US106-2020-mRNA-1273-P301000001'		

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Cardiac failure aggravated - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Mar 2021 15:13:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 15:13:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure acute, LLT: Cardiac failure acute - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 04:33:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 04:33:45
Data point term sent to Coder	System	23 Sep 2020 17:39:03
User entered 'Acute cardiac heart failure exacerbation'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '02 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '13 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:15:11
	(b) (4), (b) (6)	24 Nov 2020 22:03:07
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'updated' (Site from Safety).	Michele McCullough (b) (4)	24 Nov 2020 21:37:19
DataPoint Un-verified.	Michele McCullough (b) (4)	24 Nov 2020 21:37:14
User entered 'Grade 4 (Grade 4)' reason for change: Per Query Resolution	Michele McCullough (b) (4)	24 Nov 2020 21:37:14
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:07:44
	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

US3482145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

US3482145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

US3482145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

US3482145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

US3482145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '02 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

US3482145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 12:51:16
Query 'PV query: Discharge date for event of acute cardiac heart failure exacerbation was reported as 02 Sep 2020, the same day the subject was admitted. Please clarify if this should be updated to 13 Sep 2020 to match discharge date for event of sepsis related to Streptococcus bacteremia.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 12:51:13
User entered '13 Sep 2020' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	05 Oct 2020 13:22:26
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:49:40
User opened query 'PV query: Discharge date for event of acute cardiac heart failure exacerbation was reported as 02 Sep 2020, the same day the subject was admitted. Please clarify if this should be updated to 13 Sep 2020 to match discharge date for event of sepsis related to Streptococcus bacteremia.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:47:50
User entered '02 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

US3482145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '3'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

US3482145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

US3482145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:28:06
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	23 Sep 2020 17:38:35
User entered 'Not Related (NOT RELATED)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Not Related (NOT RELATED)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding Dosing Discontinuation record to match this information. Please review and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 04:35:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:25:32
User closed query 'per source the IP was with drawn, please review.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:25:28
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		10 Nov 2020 16:23:35
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	10 Nov 2020 16:23:35
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 16:23:35
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	10 Nov 2020 16:20:38
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 16:20:38
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 16:20:38
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:17:34

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding Dosing Discontinuation record to match this information. Please review and update applicable details accordingly. Otherwise, clarify.' answered with 'reviewed and updated' (Site from DM). User entered 'None (NONE)' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	09 Nov 2020 21:09:09
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding Dosing Discontinuation record to match this information. Please review and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	02 Nov 2020 17:51:41
Query 'per source the IP was with drawn, please review.' answered with 'done' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 01:07:50
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	28 Oct 2020 19:31:33
DataPoint Verified.	Sarah Bechnak (b) (4) (b) (4)	28 Oct 2020 19:31:25
User opened query 'per source the IP was with drawn, please review.' (Site from CRA).	Sarah Bechnak (b) (4) (b) (4)	28 Oct 2020 19:31:25
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	28 Oct 2020 19:06:21
	Sarah Bechnak (b) (4) (b) (4)	21 Oct 2020 20:13:14
	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 18:46:47
User closed query 'PV Query: Urine culture was positive, <10,000 CFU/ml. Please consider reporting additional SAE Urinary tract infection.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 18:46:42
User closed query 'PV Query: PV Query: Please provide treatment given for the event of acute cardiac heart failure exacerbation 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)	22 Oct 2020 18:46:36
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'done' (Site from Safety).	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:39:20
Query 'PV Query: PV Query: Please provide treatment given for the event of acute cardiac heart failure exacerbation 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 'done. Medications added. No procedural/ surgical treatment.' (Site from Safety).	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:23:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Urine culture was positive, <10,000 CFU/ml. Please consider reporting additional SAE Urinary tract infection.' answered with 'Urine culture showed microorganisms <10,000 CFU/ML, not considered relevant since no further growth.' (Site from Safety).	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 14:01:34
User opened query 'PV Query: Urine culture was positive, <10,000 CFU/ml. Please consider reporting additional SAE Urinary tract infection.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:12:36
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:12:15
User opened query 'PV Query: PV Query: Please provide treatment given for the event of acute cardiac heart failure exacerbation 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)	15 Oct 2020 12:11:50
Query 'PV Query: Urine culture was positive, <10,000 CFU/ml. Please consider reporting additional SAE Urinary tract infection.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 12:51:21
User opened query 'PV Query: Urine culture was positive, <10,000 CFU/ml. Please consider reporting additional SAE Urinary tract infection.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 13:48:50
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Sep 2020 17:39:52
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	23 Sep 2020 17:39:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT, WITH A PAST MEDICAL HISTORY SIGNIFICANT FOR CHRONIC SYSTOLIC HEART FAILURE WITH EJECTION FRACTION OF 25% WAS ADMITTED TO THE EMERGENCY DEPARTMENT ON 09/02/2020 FOR ALTERED MENTAL STATUS, BACTEREMIA, AND ACUTE CARDIAC HEART FAILURE EXACERBATION. PATIENT PRESENTED WITH: -WBC COUNT: 13.L 10E3/MCL LACTIC ACID: 3.6 MMOL/L BNP: <4700 PG/ML COVID BY PCR ON 09/02/2020: NEGATIVE URINE CULTURE: POSITIVE <10,000 CFU/ML EJECTION FRACTION ON ECHOCARDIOGRAM: 25%-30% BLOOD CULTURE: POSITIVE FOR BETA HEMOLYTIC STREPTOCOCCUS GROUP C. SUBJECT TREATED WITH CEFTRIAXONE THEN SHIFTED TO LEVOFLOXACIN (COURSE DONE ON SEP 16). VITALS ON ADMISSION: T: 37.8° ORAL. BP: 105/72 MMHG, HR: 75 BPM, SPO2: 100%. PHYSICAL EXAM ON ADMISSION TO ED: HEENT: NORMOCEPHALIC, ATRAUMATIC, PUPILS EQUALLY ROUND AND REACTIVE TO LIGHT, NO JVD, NO LYMPHADENOPATHY. LUNGS: CLEAR TO AUSCULTATION BILATERALLY. CVS: IRREGULAR RATE AND RHYTHM, NO MURMURS OR RUBS. ABD: NABS, SOFT, NONTENDER, NON DISTENDED. EXT: NO CLUBBING, NO CYANOSIS, +2 EDEMA OF LOWER EXTREMITIES BILATERALLY. NEURO: ALERT AND ORIENTED TO PERSON, PLACE, AND SITUATION. LETHARGIC BUT AROUSABLE, NO FOCAL NEUROLOGIC DEFICITS.'	Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:39:52
Entry Error User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). User entered empty.	System Sarah Bechnak (b) (4) (b) (4)	23 Sep 2020 17:38:35 23 Sep 2020 17:38:35

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 17:38:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:47:49

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 17:21:12
User entered	System	17 Nov 2020 17:21:03
'USA-US106-2020-mRNA-1273-P301000005'		
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 17:21:03
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 17:21:03
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:21:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 13:44:42
User entered	(b) (4), (b) (6)	23 Oct 2020 13:44:38
'USA-US106-2020-mRNA-1273-P301000001'		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:47:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 22:04:06
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia aggravated - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 16:00:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 16:00:32
Data point term sent to Coder	System	11 Nov 2020 17:44:33
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	11 Nov 2020 17:44:03
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'changed terminology of AE' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 17:44:03
Data point term sent to Coder	System	11 Nov 2020 17:42:29
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:21
User entered 'Exacerbation of Anemia' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:42:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:49:20
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	11 Nov 2020 16:35:35
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:13:40
Data point term sent to Coder	System	10 Nov 2020 21:26:49
Coding entries removed.	(b) (4), (b) (6)	10 Nov 2020 21:26:25
User entered 'PRE-SYNCOPE secondary to anemia' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:26:25
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Pre-syncope - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 20:41:41

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Nov 2020 20:41:41
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Query 'PV Query: Please consider updating the event	Mary Bower (b) (4)	10 Nov 2020 20:40:49
term to the underlying cause/etiology of the event.'	(b) (4)	
answered with 'updated' (Site from Safety).		
Data point term sent to Coder	System	10 Nov 2020 20:40:20
DataPoint Un-verified.	Mary Bower (b) (4)	10 Nov 2020 20:39:43
	(b) (4)	
Coding entries removed.	Mary Bower (b) (4)	10 Nov 2020 20:39:43
	(b) (4)	
User entered 'pre-syncope' reason for change: Data	Mary Bower (b) (4)	10 Nov 2020 20:39:43
Entry Error	(b) (4)	
User opened query 'PV Query: Please consider	(b) (4), (b) (6)	30 Oct 2020 16:12:46
updating the event term to the underlying		
cause/etiology of the event.' (Site from Safety).		
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User coded data point as SOC: General disorders and	Coder Import (b) (4)	22 Oct 2020 15:56:38
administration site conditions, HLGT: General	(b) (4)	
system disorders NEC, HLT: Asthenic conditions,		
PT: Asthenia, LLT: Weakness - version		
MedDRA\\23.0.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	22 Oct 2020 15:56:38
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	22 Oct 2020 15:55:32
User entered 'Weakness'	Sarah Bechnak (b) (4)	22 Oct 2020 15:54:33
	(b) (4)	

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Folder: Adverse Events

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
	(b) (4)	
DataPoint Un-verified.	Sarah Bechnak (b) (4)	26 Jan 2021 15:06:41
	(b) (4)	
User entered '21 Oct 2020' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Jan 2021 15:06:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '22 Oct 2020'	Sarah Bechnak (b) (4)	22 Oct 2020 15:54:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 15:54:33

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Form: Adverse Events (3)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:48:55
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:02:00
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	22 Oct 2020 15:54:33
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:49:01
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:13:48
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date provided ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:02:39
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:00
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:02:00
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 16:11:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4)	22 Oct 2020 15:54:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:47:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query 'per source the grade is 3, please review. ' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:31:49
	(b) (4), (b) (6)	10 Nov 2020 16:17:34
Query 'per source the grade is 3, please review. ' answered with 'done' (Site from CRA).	Sarah Bechnak (b) (4)	28 Oct 2020 19:27:35
DataPoint Un-verified.	(b) (4)	
	Sarah Bechnak (b) (4)	28 Oct 2020 19:26:40
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Sarah Bechnak (b) (4)	28 Oct 2020 19:26:40
	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User opened query 'per source the grade is 3, please review. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 19:08:17
User entered 'Grade 4 (Grade 4)'	(b) (4)	
	Sarah Bechnak (b) (4)	22 Oct 2020 15:54:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 10:48:58
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'admission date is there. Discharge date not known, still hospitalized.' (Site from System).	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:58:00
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	22 Oct 2020 15:54:33
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '22 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:47:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:49:08
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:13:57
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'subject was discharged on date provided.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:02:43
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:00
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:02:00
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 16:11:59
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4)	22 Oct 2020 15:54:33
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Not Related (NOT RELATED)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Not Related (NOT RELATED)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Not Applicable (NOT APPLICABLE)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Form: Adverse Events (3)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query 'PV Query: Please confirm which concomitant medication was considered treatment for this event (none had indication of "exacerbation of anemia") or confirm if any other treatment was given.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 14:29:30
Query 'PV Query: Please confirm which concomitant medication was considered treatment for this event (none had indication of "exacerbation of anemia") or confirm if any other treatment was given.' answered with 'reviewed and updated' (Site from Safety).	Sarah Bechnak (b) (4) (b) (4)	22 Dec 2020 14:51:25
User opened query 'PV Query: Please confirm which concomitant medication was considered treatment for this event (none had indication of "exacerbation of anemia") or confirm if any other treatment was given.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 21:27:29
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the therapeutic procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 05:19:22
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the therapeutic procedure as appropriate. Otherwise, clarify.' answered with 'ONLY CON MED' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:08:30
DataPoint Un-verified.	Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:08:04
User entered '0' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:08:04
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the therapeutic procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 13:26:00
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '1'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:49:14
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:14:03
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'subject's hospitalization was resolved' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:03:05
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:02:00
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 16:12:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:54:33

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query 'Per DM CLR: SAE Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:05:46
User closed query 'Per DM CLR: SAE Narrative = TROP NEGATIVE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 15:05:44
User closed query 'Per DM CLR: SAE Narrative = PATIENT STARTED ON PROTONIX BOLUS AND DRIP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 15:05:42
User closed query 'Per DM CLR: SAE Narrative = METALLIC PROSTHETIC VALVE - not on MH. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 15:05:40
User closed query 'Per DM CLR: SAE Narrative = 10/21 EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 15:05:38
User closed query 'Per DM CLR: SAE Narrative = EDG AND COLONOSCOPY PERFORMED 3-6 MONTHS AGO. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 15:05:34
User closed query 'Per DM CLR: SAE Narrative = NOTED ON LABS TO HAVE A BUN/CR OF 68/1.0. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 15:05:32

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Generated On: 09 Jun 2021 17:47:49

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = CORONARY ARTERY DISEASE. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 15:05:30
User closed query 'PV Query: Please provide work-ups of the reported anemia, including stool OBT, types of anemia (microcytic, normocytic, or macrocytic), blood chemistry (blood iron, folate, vitamin B12, reticulocyte), bone marrow study, etc).' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 16:20:11
User closed query 'PV Query: Please consider if GI Consult notes of "GI Bleed" meets criteria for separate AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 16:20:03
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 16:19:56
Query 'Per DM CLR: SAE Narrative = PATIENT STARTED ON PROTONIX BOLUS AND DRIP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'REVEIWED AND UPDATED. PROTONIX ADDED TO CON MEDS' (Site from DM).	Sarah Bechnak (b) (4)	26 Jan 2021 18:58:12
Query 'Per DM CLR: SAE Narrative = TROP NEGATIVE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added blood workup in con procedure ' (Site from DM).	Sarah Bechnak (b) (4)	26 Jan 2021 18:51:38
Query 'Per DM CLR: SAE Narrative = 10/21 EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'reviewed and updated. Added to con proc ' (Site from DM).	Sarah Bechnak (b) (4)	26 Jan 2021 18:50:57

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = METALLIC PROSTHETIC VALVE - not on MH. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'reviewed and updated. med history list updated' (Site from DM).	Sarah Bechnak (b) (4)	26 Jan 2021 18:47:09
Query 'Per DM CLR: SAE Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated and reviewed. Chest x-ray added to con procedures' (Site from DM).	Sarah Bechnak (b) (4)	26 Jan 2021 18:34:34
Query 'Per DM CLR: SAE Narrative = NOTED ON LABS TO HAVE A BUN/CR OF 68/1.0. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'reviewed and updated. Captured in con procedures under blood workup' (Site from DM).	Sarah Bechnak (b) (4)	26 Jan 2021 18:32:54
Query 'Per DM CLR: SAE Narrative = EDG AND COLONOSCOPY PERFORMED 3-6 MONTHS AGO. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'EDG and colonoscopy not part of medical history. They are recorded in con procedure. ' (Site from DM).	Sarah Bechnak (b) (4)	26 Jan 2021 18:26:45
Query 'Per DM CLR: SAE Narrative = CORONARY ARTERY DISEASE. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'coronary artery disease is a pre-existing medical condition and was added to medical history. Thank you' (Site from DM).	Sarah Bechnak (b) (4)	26 Jan 2021 18:16:23

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide work-ups of the reported anemia, including stool OBT, types of anemia (microcytic, normocytic, or macrocytic), blood chemistry (blood iron, folate, vitamin B12, reticulocyte), bone marrow study, etc).' answered with ' HEMOGLOBIN WAS NOTED TO BE 6.6G/DL. FOLLOW UP HEMOGLOBIN WAS NOTED TO BE 6.3G/DL, FERRITIN LEVEL: 78NG/ML FOLATE LEVEL: 9.7 NG/ML, TOTAL IRON LEVEL: 36UG/DL. Subject had acute normocytic anemia' (Site from Safety).	Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 15:23:49

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:47:49

[Narrative](#)

Audit	User	Time (GMT)
User entered 'NARRATIVE OBTAINED FROM PHYSICIAN CONSULT NOTE AT ADMINISSON. PATIENT IS A 66 YEAR OLD MAN WITH A PAST MEDICAL HISTORY OF CONGESTIVE HEART FAILURE, HYPERTENSION, AND CORONARY ARTERY DISEASE WHO HAS BEEN HAVING MELENA AND FATIGUE SINCE EARLIER IN THE WEEK. THE PATIENT STATES HE HAD AN EDG AND COLONOSCOPY PERFORMED 3-6 MONTHS AGO AT EMORY MIDTOWN HOSPITAL. HE STATES THAT THESE RESULTS WERE NORMAL. HE ALSO STATES THAT THE PROCEDURES WERE DONE AT THE SAME TIME BECAUSE HE WAS HAVING FATIGUE AND NOT BECAUSE HE WAS HAVING MELENA. 10/21/20: PATIENT CAME TO THE ED AND WAS NOTED ON LABS TO HAVE A BUN/CR OF 68/1.0. HEMOGLOBIN WAS NOTED TO BE 6.6G/DL. FOLLOW UP HEMOGLOBIN WAS NOTED TO BE 6.3G/DL, FERRITIN LEVEL: 78NG/ML FOLATE LEVEL: 9.7 NG/ML, TOTAL IRON LEVEL: 36UG/DL CXR SHOWEDCARDIOMEGALY WITH INTACT METALLIC PROSTHETIC VALVE. PATIENT STATES THAT HE HAS HAD A VALVE REPLACEMENT IN THE PAST. 10/21 EKG SHOWS AFIB AND T-WAVE INVERSION IN LEADS I,II, V2, V45-V6. TROP NEGATIVE. GI CONSULTED FOR GI BLEED. PATIENT STARTED ON PROTONIX BOLUS AND DRIP. RECEIVED 3 UNITS OF BLOOD WHILE HOSPITALIZED. COVID 19 TESTING BY PCR DONE ON 10/22/2020 IS NEGATIVE. ' reason for change: Data Entry Error Query 'PV Query: Please consider if GI Consult notes of "GI Bleed" meets criteria for separate AE/SAE.' answered with 'GI BLEED DOES NOT MEET SEPERATE SAE REPORTING. IT WAS HAPPENING AT THE SAME TIME.' (Site from Safety).	Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 15:23:44
	Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 15:09:26

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'COVID 19 testing by PCR done on 10/22/2020 is negative' (Site from Safety).	Sarah Bechnak (b) (4)	26 Jan 2021 15:08:19
User entered 'NARRATIVE OBTAINED FROM PHYSICIAN CONSULT NOTE AT ADMINISSON. PATIENT IS A 66 YEAR OLD MAN WITH A PAST MEDICAL HISTORY OF CONGESTIVE HEART FAILURE, HYPERTENSION, AND CORONARY ARTERY DISEASE WHO HAS BEEN HAVING MELENA AND FATIGUE SINCE EARLIER IN THE WEEK. THE PATIENT STATES HE HAD AN EDG AND COLONOSCOPY PERFORMED 3-6 MONTHS AGO AT EMORY MIDTOWN HOSPITAL. HE STATES THAT THESE RESULTS WERE NORMAL. HE ALSO STATES THAT THE PROCEDURES WERE DONE AT THE SAME TIME BECAUSE HE WAS HAVING FATIGUE AND NOT BECAUSE HE WAS HAVING MELENA. 10/21/20: PATIENT CAME TO THE ED AND WAS NOTED ON LABS TO HAVE A BUN/CR OF 68/1.0. HEMOGLOBIN WAS NOTED TO BE 6.6G/DL. FOLLOW UP HEMOGLOBIN WAS NOTED TO BE 6.3G/DL. CXR SHOWED CARDIOMEGALY WITH INTACT METALLIC PROSTHETIC VALVE. PATIENT STATES THAT HE HAS HAD A VALVE REPLACEMENT IN THE PAST. 10/21 EKG SHOWS AFIB AND T-WAVE INVERSION IN LEADS I,II, V2, V45-V6. TROP NEGATIVE. GI CONSULTED FOR GI BLEED. PATIENT STARTED ON PROTONIX BOLUS AND DRIP. RECEIVED 3 UNITS OF BLOOD WHILE HOSPITALIZED. COVID 19 testing by PCR done on 10/22/2020 is negative' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	26 Jan 2021 15:08:15

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = PATIENT STARTED ON PROTONIX BOLUS AND DRIP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:53:32
User opened query 'Per DM CLR: SAE Narrative = TROP NEGATIVE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:53:25
User opened query 'Per DM CLR: SAE Narrative = 10/21 EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:53:19
User opened query 'Per DM CLR: SAE Narrative = METALLIC PROSTHETIC VALVE - not on MH. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:53:11
User opened query 'Per DM CLR: SAE Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:53:04
User opened query 'Per DM CLR: SAE Narrative = NOTED ON LABS TO HAVE A BUN/CR OF 68/1.0. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:52:56
User opened query 'Per DM CLR: SAE Narrative = EDG AND COLONOSCOPY PERFORMED 3-6 MONTHS AGO. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:52:50

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = CORONARY ARTERY DISEASE. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:52:44
User opened query 'PV Query: Please provide work-ups of the reported anemia, including stool OBT, types of anemia (microcytic, normocytic, or macrocytic), blood chemistry (blood iron, folate, vitamin B12, reticulocyte), bone marrow study, etc).' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 19:15:02
Query ' Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 19:09:39
Query 'PV Query: Please provide work-ups of the reported anemia, including stool OBT, types of anemia (microcytic, normocytic, or macrocytic), blood chemistry (blood iron, folate, vitamin B12, reticulocyte), bone marrow study, etc).' canceled (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 19:09:23
User opened query 'PV Query: Please provide work-ups of the reported anemia, including stool OBT, types of anemia (microcytic, normocytic, or macrocytic), blood chemistry (blood iron, folate, vitamin B12, reticulocyte), bone marrow study, etc).' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 19:08:36
User opened query 'PV Query: Please consider if GI Consult notes of "GI Bleed" meets criteria for separate AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 19:05:47
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 19:05:35
User opened query ' Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 19:04:55

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[Narrative](#)

Audit	User	Time (GMT)
User closed query '*REQUERY* PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 16:39:14
User closed query '*REQUERY* PV Query: Please provide results of pertinent consult notes(cardiology, pulmonology, nephrology) or discharge summary when available. Thank you, (b) (6) (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 16:39:04
User entered 'NARRATIVE OBTAINED FROM PHYSICIAN CONSULT NOTE AT ADMINISSON. PATIENT IS A 66 YEAR OLD MAN WITH A PAST MEDICAL HISTORY OF CONGESTIVE HEART FAILURE, HYPERTENSION, AND CORONARY ARTERY DISEASE WHO HAS BEEN HAVING MELENA AND FATIGUE SINCE EARLIER IN THE WEEK. THE PATIENT STATES HE HAD AN EDG AND COLONOSCOPY PERFORMED 3-6 MONTHS AGO AT EMORY MIDTOWN HOSPITAL. HE STATES THAT THESE RESULTS WERE NORMAL. HE ALSO STATES THAT THE PROCEDURES WERE DONE AT THE SAME TIME BECAUSE HE WAS HAVING FATIGUE AND NOT BECAUSE HE WAS HAVING MELENA. 10/21/20: patient came to the ED and was noted on labs to have a BUN/Cr of 68/1.0. Hemoglobin was noted to be 6.6g/dL. Follow up hemoglobin was noted to be 6.3g/dL. CXR showed cardiomegaly with intact metallic prosthetic valve. Patient states that he has had a valve replacement in the past. 10/21 EKG shows afib and T-wave inversion in leads I,II, V2, V45-V6. Trop negative. GI consulted for GI Bleed. Patient started on protonix bolus and drip. Received 3 units of blood while hospitalized.' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 18:19:13

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Query '*REQUERY* PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with ' 10/21/20: patient came to the emergency department and was noted on labs to have BUN/Cr of 68/1.0. hemoglobin was noted to be 6.6g/dl. follow up hemoglobin was noted to be 6.3g/dl. ' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 18:06:33
Query '*REQUERY* PV Query: Please provide results of pertinent consult notes(cardiology, pulmonology, nephrology) or discharge summary when available. Thank you, (b) (6) answered with '10/21/20: CXR showed cardiomegaly with an intact metallic prosthetic valve. patient states he has had a valve replacement in the past. ' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 18:06:26
User entered 'Narrative obtained from Physician Consult Note at Adminisson. Patient is a 66 year old man with a past medical history of congestive heart failure, hypertension, and coronary artery disease who has been having melena and fatigue since earlier in the week. the patient states he had an EDG and colonoscopy performed 3-6 months ago at Emory Midtown Hospital. he states that these results were normal. he also states that the procedures were done at the same time because he was having fatigue and not because he was having melena.' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 17:58:30
User opened query '*REQUERY* PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 18:18:07
User opened query '*REQUERY* PV Query: Please provide results of pertinent consult notes(cardiology, pulmonology, nephrology) or discharge summary when available. Thank you, (b) (6) (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 18:17:53
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 14:29:36

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Audit	User	Time (GMT)
User closed query 'PV Query: Please provide results of pertinent consult notes(cardiology, pulmonology, nephrology) or discharge summary when available. Thank you.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 14:29:34
Query 'PV Query: Please provide results of pertinent consult notes(cardiology, pulmonology, nephrology) or discharge summary when available. Thank you.' answered with 'Pending medical records. They will be provided as soon as they are available.' (Site from Safety).	Sarah Bechnak (b) (4)	22 Dec 2020 14:46:13
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Pending medical records. Will be faxed as soon as available.' (Site from Safety).	Sarah Bechnak (b) (4)	22 Dec 2020 14:44:10
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 21:26:56
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 15:39:51
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 'TREATMENT RECORDED IN CON MEDS' (Site from Safety).	Sarah Bechnak (b) (4)	10 Dec 2020 17:09:07
User opened query 'PV Query: Please provide results of pertinent consult notes(cardiology, pulmonology, nephrology) or discharge summary when available. Thank you.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:13:51

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[Narrative](#)

Audit	User	Time (GMT)
Query 'IQVIA medical safety query: Please provide results of pertinent consult notes(cardiology, pulmonology, nephrology) or discharge summary when available. Thank you, (b) (6) canceled (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:03:47
User opened query 'IQVIA medical safety query: Please provide results of pertinent consult notes(cardiology, pulmonology, nephrology) or discharge summary when available. Thank you, (b) (6) (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:01:53
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)	24 Nov 2020 19:01:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'SUBJECT COMING IN FOR VISIT 3, reported as soon as he arrived that he feels very weak and that he thinks he should go to the hospital. Ambulance called, subject taken to the Emergency department and admitted to an inpatient floor.' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	22 Oct 2020 15:57:01
User entered 'Subject coming in for visit 3,'	Sarah Bechnak (b) (4)	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '0'	System	22 Oct 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (4)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 17:22:42
User entered	System	17 Nov 2020 17:22:35
'USA-US106-2020-mRNA-1273-P301000006'		
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 17:22:35
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 17:22:35
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:22:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 13:45:15
User entered	(b) (4), (b) (6)	23 Oct 2020 13:45:11
'USA-US106-2020-mRNA-1273-P301000001'		

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:16:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:16:32
Data point term sent to Coder	System	22 Oct 2020 17:27:25
User entered 'Gout exacerbation in right knee'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

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Folder: Adverse Events

Form: Adverse Events (4)

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

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Folder: Adverse Events

Form: Adverse Events (4)

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

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Folder: Adverse Events

Form: Adverse Events (4)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	22 Oct 2020 17:27:10
User entered '26 Sep 2020' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:27:10
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	22 Oct 2020 17:26:41
User entered '26 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	22 Oct 2020 17:27:10
User entered '30 Sep 2020' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:27:10
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	22 Oct 2020 17:26:41
User entered '30 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	22 Oct 2020 17:27:10
User entered '26 Sep 2020' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:27:10
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	22 Oct 2020 17:26:41
User entered '26 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	22 Oct 2020 17:27:10
User entered '30 Sep 2020' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:27:10
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	22 Oct 2020 17:26:41
User entered '30 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '3'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Not Related (NOT RELATED)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Not Related (NOT RELATED)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Not Applicable (NOT APPLICABLE)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Subject went to the emergency department complaining of right knee pain and swelling affecting his ability to ambulate. Patient presented with elevated levels of uric acid (10.5 mg/dl), diagnosed with acute gout flare, improved on Prednisone. Subject was also found to have Acute exacerbation of stage III kidney disease, hyperkalemia, and acidosis PH: 7.14, Lactate 2.51.'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered 'I'	System	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered 'I'	System	22 Oct 2020 17:26:41

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 17:23:21
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 17:23:15
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:15
User entered	(b) (4), (b) (6)	17 Nov 2020 17:23:15
'USA-US106-2020-mRNA-1273-P301000006'		
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:15:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 13:45:46
User entered	(b) (4), (b) (6)	23 Oct 2020 13:45:41
'USA-US106-2020-mRNA-1273-P301000001'		

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:38:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:38:40
Data point term sent to Coder	System	22 Oct 2020 17:33:34
User entered 'Acute exacerbation of chronic kidney disease stage III'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '26 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '30 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '26 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '30 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

US3482145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '3'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Not Related (NOT RELATED)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Not Related (NOT RELATED)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Not Applicable (NOT APPLICABLE)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:15:41
User entered 'SUBJECT WENT TO THE EMERGENCY DEPARTMENT COMPLAINING OF RIGHT KNEE PAIN AND SWELLING AFFECTING HIS ABILITY TO AMBULATE. PATIENT PRESENTED WITH ELEVATED LEVELS OF URIC ACID (10.5 MG/DL), DIAGNOSED WITH ACUTE GOUT FLARE, IMPROVED ON PREDNISONE. SUBJECT WAS ALSO FOUND TO HAVE ACUTE EXACERBATION OF STAGE III KIDNEY DISEASE, HYPERKALEMIA (POSTASSIUM LEVEL: 8.4 MMOL/L), AND ACIDOSIS PH: 7.14, LACTATE 2.51.' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:35:52
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Oct 2020 17:34:17
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Oct 2020 17:34:17
User entered 'SUBJECT WENT TO THE EMERGENCY DEPARTMENT COMPLAINING OF RIGHT KNEE PAIN AND SWELLING AFFECTING HIS ABILITY TO AMBULATE. PATIENT PRESENTED WITH ELEVATED LEVELS OF URIC ACID (10.5 MG/DL), DIAGNOSED WITH ACUTE GOUT FLARE, IMPROVED ON PREDNISONE. SUBJECT WAS ALSO FOUND TO HAVE ACUTE EXACERBATION OF STAGE III KIDNEY DISEASE, HYPERKALEMIA, AND ACIDOSIS PH: 7.14, LACTATE 2.51.' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:34:17
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Oct 2020 17:33:26
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:33:26

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered 'I'	System	22 Oct 2020 17:33:26

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Folder: Adverse Events

Form: Adverse Events (6)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 18:06:10
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 17:19:44
User entered	System	17 Nov 2020 17:19:34
'USA-US106-2020-mRNA-1273-P301000004'		
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 17:19:34
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:19:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:34:59
User entered	(b) (4), (b) (6)	12 Nov 2020 15:34:55
'USA-US106-2020-mRNA-1273-P301000001'		

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:24:48
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure acute, LLT: Acute decompensated heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 12:52:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 12:52:53
Data point term sent to Coder	System	13 Jan 2021 20:39:17
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'REVIEWED AND UPDATED' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	13 Jan 2021 20:38:57
DataPoint Un-verified.	Sarah Bechnak (b) (4) (b) (4)	13 Jan 2021 20:38:41
Coding entries removed.	Sarah Bechnak (b) (4) (b) (4)	13 Jan 2021 20:38:41
User entered 'WORSENING OF ACUTE DECOMPENSATED HEART FAILURE' reason for change: Per Query Resolution	Sarah Bechnak (b) (4) (b) (4)	13 Jan 2021 20:38:41
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 07:48:13
User closed query 'PV Query: Please consider updating the event term to the final diagnosis to "acute decompensated heart failure" to not include the symptom of "shortness of breath" in the event term.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:15:37
User closed query 'Per MM: Please split terms and record as separate Adverse Events.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:27:06

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:03
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure acute, LLT: Acute decompensated heart failure - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 21:54:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	24 Nov 2020 21:54:58
Data point term sent to Coder	System	24 Nov 2020 21:54:01
Query 'Per MM: Please split terms and record as separate Adverse Events.' answered with 'updated' (Site from DM).	Michele McCullough	24 Nov 2020 21:53:30
Query 'PV Query: Please consider updating the event term to the final diagnosis to "acute decompensated heart failure" to not include the symptom of "shortness of breath" in the event term.' answered with 'updated' (Site from Safety).	(b) (4)	24 Nov 2020 21:53:26
DataPoint Un-verified.	Michele McCullough	24 Nov 2020 21:53:03
Coding entries removed.	(b) (4)	24 Nov 2020 21:53:03
User entered 'ACUTE DECOMPENSATED HEART FAILURE' reason for change: Per Query Resolution	Michele McCullough	24 Nov 2020 21:53:03
User opened query 'PV Query: Please consider updating the event term to the final diagnosis to "acute decompensated heart failure" to not include the symptom of "shortness of breath" in the event term.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:21:49
User opened query 'Per MM: Please split terms and record as separate Adverse Events.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:38:35
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:53:16
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure acute, LLT: Acute decompensated heart failure - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 14:47:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	11 Nov 2020 14:47:33
Data point term sent to Coder	System	11 Nov 2020 14:44:46
User entered 'Shortness of Breath due to acute decompensated heart failure'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered '09 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

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

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered '10 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered '09 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered '10 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 14:44:27
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	11 Nov 2020 14:44:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 14:44:27
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 14:44:14
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:17:51
User closed query "" Per DM CLR: SAE Narrative = TROPONIN:0.03 BNP: 758 CR: 1.83, DROPPED TO 1.6. NORMAL EKG READING. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. " ' (Site from DM). Query "" Per DM CLR: SAE Narrative = TROPONIN:0.03 BNP: 758 CR: 1.83, DROPPED TO 1.6. NORMAL EKG READING. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. " ' answered with 'EKG ADDED TO CON PROC AND BLOOD WORK ADDED TO CON PROCEDURE. TROPONIN LEVEL SHOULD FALL UNDER BLOOD WORK.' (Site from DM).	(b) (4) (b) (4), (b) (6) Sarah Bechnak (b) (4) (b) (4)	28 Jan 2021 15:06:37 26 Jan 2021 18:59:07
User opened query "" Per DM CLR: SAE Narrative = TROPONIN:0.03 BNP: 758 CR: 1.83, DROPPED TO 1.6. NORMAL EKG READING. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. " ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:54:00
User closed query 'PV Query: Please provide results of lab/diagnostic test performed in evaluation of acute decompensated heart failure (e.g. BNP, echocardiogram, EKG, etc) ' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 15:33:50
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 15:33:47
Query 'PV Query: Please provide results of lab/diagnostic test performed in evaluation of acute decompensated heart failure (e.g. BNP, echocardiogram, EKG, etc) ' answered with 'UPDATED' (Site from Safety).	Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:22:20

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'UPDATED' (Site from Safety). DataPoint Un-verified.	Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:22:03
	Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:21:52
User entered 'SUBJECT PRESENTED TO ED ON 11/9/2020 WITH SHORTNESS OF BREATH AND FELT LIKE HE HAD A LOT OF FLUID ON HIM. AFTER ADMISSION HE WAS GIVEN IV FUROSEMIDE ON 11/9 AND 11/10 AND WAS FEELING BETTER. COVID PCR NEGATIVE ON 09NOV2020. tROPONIN:0.03 BNP: 758 CR: 1.83, DROPPED TO 1.6. NORMAL EKG READING' reason for change: Per Query Resolution	Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:21:52
User opened query 'PV Query: Please provide results of lab/diagnostic test performed in evaluation of acute decompensated heart failure (e.g. BNP, echocardiogram, EKG, etc) ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 11:06:16
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:15:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:07:05
DataPoint Un-verified.	Michele McCullough (b) (4)	24 Nov 2020 22:04:28
User entered 'SUBJECT PRESENTED TO ED ON 11/9/2020 WITH SHORTNESS OF BREATH AND FELT LIKE HE HAD A LOT OF FLUID ON HIM. AFTER ADMISSION HE WAS GIVEN IV FUROSEMIDE ON 11/9 AND 11/10 AND WAS FEELING BETTER. COVID PCR negative on 09NOV2020.' reason for change: Data Entry Error	Michele McCullough (b) (4)	24 Nov 2020 22:04:28

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Tested negative for COVID by PCR in hospital on 09Nov2020' (Site from Safety).	Michele McCullough (b) (4)	24 Nov 2020 22:02:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:21:34
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:21:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:53:16
User entered 'Subject presented to ED on 11/9/2020 with shortness of breath and felt like he had a lot of fluid on him. After admission he was given IV furosemide on 11/9 and 11/10 and was feeling better.'	(b) (4), (b) (6)	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 14:44:14

US3482145

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 14:44:14

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:17:03
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:02:27

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 17:59:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 17:59:04
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 18:03:19
User entered 'Atorvastatin Calcium'	Sarah Bechnak (b) (4)	26 Aug 2020 18:03:11
	(b) (4)	

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Hyperlipidemia'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:59:48
User closed query 'per source the dose is 80 mg, please review.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:59:46
Query 'per source the dose is 80 mg, please review.' answered with 'updated and reviewed' (Site from CRA).	Sarah Bechnak (b) (4)	12 Nov 2020 17:07:22
DataPoint Un-verified.	(b) (4)	
	Sarah Bechnak (b) (4)	12 Nov 2020 17:07:13
User entered '80' reason for change: Per Query Resolution	(b) (4)	
	Sarah Bechnak (b) (4)	12 Nov 2020 17:07:13
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User opened query 'per source the dose is 80 mg, please review.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 19:18:13
User entered '40' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	12 Sep 2020 01:11:19
User entered '80'	Sarah Bechnak (b) (4)	26 Aug 2020 18:03:11
	(b) (4)	

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'UN UNK 2019'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:03:11

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Nov 2020 06:43:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 06:43:01
Data point term sent to Coder	System	12 Nov 2020 18:34:41
Data point term sent to Coder	System	12 Nov 2020 17:10:15
Coding entries removed.	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 17:09:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:10
Data point term sent to Coder	System	26 Aug 2020 18:04:21
User entered 'FUROSEMIDE'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of WATER RETENTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 09:57:59
User entered 'WATER RETENTION IN feet RELATED TO GOUT' reason for change: Per Query Resolution	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:33:51
Query 'Per DM CLR: Please update the indication to reflect the location and type of WATER RETENTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated and reviewed' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 17:09:58
DataPoint Un-verified.	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 17:09:26
User entered 'WATER RETENTION in bilateral lower extremities related to gout' reason for change: Per Query Resolution	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 17:09:26
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of WATER RETENTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:54:13
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Water retention'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '40'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'twice daily (BID)' reason for change:	Sarah Bechnak (b) (4)	12 Sep 2020 01:12:33
Data Entry Error	(b) (4)	
User entered 'as needed (PRN)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'UN UNK 2015'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '2'	System	12 Sep 2020 01:12:33
User entered empty.	System	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 01:12:33
User entered empty.	System	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 01:12:33
User entered empty.	System	26 Aug 2020 18:03:49

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:10
Data point term sent to Coder	System	26 Aug 2020 18:05:23
User entered 'LISINOPRIL'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Hypertention'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '10'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'UN UNK 2015'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:13:51
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Sep 2020 01:14:10
User entered 'un UNK 2020' reason for change:	Sarah Bechnak (b) (4)	12 Sep 2020 01:14:10
Data Entry Error	(b) (4)	
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Sep 2020 01:13:51
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User entered '1'	System	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User entered '1'	System	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:09:41
User entered '804 (804)'	System	26 Aug 2020 18:04:33

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:06:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:06:33
Data point term sent to Coder	System	22 Oct 2020 17:36:39
Coding entries removed.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:36:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:10
Data point term sent to Coder	System	26 Aug 2020 18:05:24
User entered 'Colchicine'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User closed query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Knees, Right Elbow, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:52:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
Query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Knees, Right Elbow, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'DONE' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:36:32
User entered 'GOUT IN BOTH KNEES' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 17:36:20
User opened query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Knees, Right Elbow, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:24:00
Query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Knees, Right Elbow, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 05:09:36
User opened query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Knees, Right Elbow, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 05:09:32
User entered 'Gout'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0.6'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'as needed (PRN)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'UN UNK 2015'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:05:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:13
Data point term sent to Coder	System	26 Aug 2020 18:06:25
User entered 'Multivitamin'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Health maintenance'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'tablet (TABLET)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '26 Aug 2020'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:05:43

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 06:04:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 06:04:43
Data point term sent to Coder	System	12 Sep 2020 01:10:08
User entered 'carvedilol'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'chronic systolic heart failure'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '3.125'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'twice daily (BID)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '2'	System	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 01:09:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 01:17:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 01:17:46
Data point term sent to Coder	System	12 Sep 2020 01:17:10
User entered 'aspirin'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'health maintenance'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '81'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 01:16:19

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 06:02:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 06:02:42
Data point term sent to Coder	System	12 Sep 2020 01:19:13
User entered 'ceftriaxone'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'sepsis due TO BETA HEMOLYTIC STREPTOCOCCUS BACTEREMIA'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '2'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'g (g)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User closed query 'Per CDM: Daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:09:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
Query 'Per CDM: Daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'done' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:30:16
User entered 'once daily (QD)' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:30:08
User opened query 'Per CDM: Daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:30:02
User entered 'other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty; reason for change Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:30:08
User entered 'EVERY 24 HOURS'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Intravenous (INTRAVENOUS)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'l'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:30:25
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '13 Sep 2020' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	14 Sep 2020 13:30:25
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User entered '1'	System	22 Oct 2020 15:30:08
User entered empty.	System	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User entered '1'	System	22 Oct 2020 15:30:08
User entered empty.	System	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:03:27
User entered '804 (804)'	System	22 Oct 2020 15:30:08
User entered empty.	System	12 Sep 2020 01:18:37

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 05:53:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 05:53:47
Data point term sent to Coder	System	12 Sep 2020 01:20:14
User entered 'FERROUS SULFATE'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'MACROCYTIC ANEMIA'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '325'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'three times daily (TID)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '3'	System	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 01:20:05

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE;SALMETEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 05:46:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 05:46:49
Data point term sent to Coder	System	12 Sep 2020 01:24:14
User entered 'FLUTICASONE- SALMETEROL HFA 230/21'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '2'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'puff (PUFF)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'twice daily (BID)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Nasal (NASAL)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '2'	System	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 01:23:56

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 05:41:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 05:41:50
Data point term sent to Coder	System	12 Sep 2020 01:27:15
User entered 'HEPARIN'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'DEEP VEIN THROMBOSIS PROPHYLAXIS'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '5000'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'UNITS'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User closed query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:51:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
Query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'done' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:32:52
User entered 'three times daily (TID)' reason for change: Per Query Resolution	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:32:45
User opened query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:30:37
User entered 'other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty; reason for change Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:32:45
User entered 'EVERY 8 HOURS'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Subcutaneous (SUBCUTANEOUS)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '3'	System	22 Oct 2020 15:32:45
User entered empty.	System	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 15:32:45
User entered empty.	System	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 15:32:45
User entered empty.	System	12 Sep 2020 01:26:28

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Nov 2020 07:04:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 07:04:02
Data point term sent to Coder	System	12 Nov 2020 18:32:37
Coding entries removed.	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:32:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 04:42:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 04:42:45
Data point term sent to Coder	System	12 Sep 2020 01:29:15
User entered 'PANTOPRAZOLE'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:18:50
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	20 Nov 2020 08:18:17
' (Site from DM).		
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	Sarah Bechnak (b) (4)	12 Nov 2020 18:33:24
' answered with 'updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Sarah Bechnak (b) (4)	12 Nov 2020 18:32:06
	(b) (4)	
User entered 'Ulcer PROPHYLAXIS' reason for change: Per Query Resolution	Sarah Bechnak (b) (4)	12 Nov 2020 18:32:06
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	29 Oct 2020 13:54:24
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'PROPHYLAXIS'	Sarah Bechnak (b) (4)	12 Sep 2020 01:28:47
	(b) (4)	

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '40'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '05 Sep 2020' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	22 Oct 2020 15:31:05
User entered empty.	(b) (4) Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	22 Oct 2020 15:31:11
User entered '0' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 15:31:11
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	22 Oct 2020 15:31:05
User entered '1'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 01:28:47

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 01:36:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 01:36:40
Data point term sent to Coder	System	12 Sep 2020 01:36:16
User entered 'ACETAMINOPHEN'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'ANALGESIA'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '325'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'EVERY 6 HOURS AS NEEDED.' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:38:03
User entered 'EVERY 6 HOURS'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 01:35:50

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 01:55:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 01:55:42
Data point term sent to Coder	System	12 Sep 2020 01:55:18
User entered 'ACETAMINoPHEN' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:54:18
Data point term sent to Coder	System	12 Sep 2020 01:38:17
User entered 'ACETAMINPHEN'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'ANALGESIA'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '650'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'EVERY 4 HOURS AS NEEDED'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Rectal (RECTAL)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 01:37:31

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 01:42:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 01:42:40
Data point term sent to Coder	System	12 Sep 2020 01:41:17
User entered 'ALBUTEROL'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '2.5'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'EVERY 6 HOURS AS NEEDED'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'I'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 01:40:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:39:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:39:48
Data point term sent to Coder	System	14 Sep 2020 13:32:08
User entered 'Levofloxacin'	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Sepsis due to beta hemolytic streptococcus bacteremia'	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '500'	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '13 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Un-verified.	(b) (4)	
	Sarah Bechnak (b) (4)	10 Dec 2020 17:03:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 17:03:29
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	14 Sep 2020 13:31:26
	(b) (4)	

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	10 Dec 2020 17:03:29
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	10 Dec 2020 17:03:18
DataPoint Un-verified.	Sarah Bechnak (b) (4)	10 Dec 2020 17:03:18
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 17:03:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4)	14 Sep 2020 13:31:26
	(b) (4)	

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User entered '1'	System	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User entered '1'	System	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:04:28
User entered '804 (804)'	System	14 Sep 2020 13:31:26

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:33:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:33:44
Data point term sent to Coder	System	22 Oct 2020 16:16:18
User entered 'Potassium chloride'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'electrolyte replacement related to chronic systolic heart failure'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '40'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'milliequivalent'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '05 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '06 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User entered '1'	System	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User entered '1'	System	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:28:30
User entered '804 (804)'	System	22 Oct 2020 16:15:24

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:27:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:27:36
Data point term sent to Coder	System	22 Oct 2020 16:17:22
User entered 'Thiamine'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'chronic systolic heart failure'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '100'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once (ONCE)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Intravenous (INTRAVENOUS)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '03 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '03 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User entered empty.	System	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User entered empty.	System	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:43
User entered empty.	System	22 Oct 2020 16:16:35

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMPICILLIN;SULBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:31:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:31:25
Data point term sent to Coder	System	22 Oct 2020 16:19:26
User entered 'Ampicillin- sulbactam'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'sepsis due to beta hemolytic streptococcus bacteremia'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '3'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'g (g)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'four times daily (QID)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Intravenous (INTRAVENOUS)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '03 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '04 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User entered '4'	System	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User entered '1'	System	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:22:21
User entered '804 (804)'	System	22 Oct 2020 16:18:29

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:13:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:13:39
Data point term sent to Coder	System	22 Oct 2020 18:16:01
User entered 'Furosemide'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Chronic systolic heart failure'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '80'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'for 3 doses'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Intravenous (INTRAVENOUS)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '03 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '04 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User entered empty.	System	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User entered empty.	System	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:35
User entered empty.	System	22 Oct 2020 18:15:22

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: CALCIUM GLUCONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 18:56:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 18:56:53
Data point term sent to Coder	System	08 Dec 2020 20:36:21
Coding entries removed.	Sarah Bechnak (b) (4)	08 Dec 2020 20:35:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: CALCIUM GLUCONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 19:44:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 19:44:12
Data point term sent to Coder	System	22 Oct 2020 18:18:02
User entered 'CALCIUM GLUCONATE'	Sarah Bechnak (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 08:16:53
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'reviewed and updated' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 20:35:52
DataPoint Un-verified.	Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 20:35:23
User entered 'ACUTE EXACERBATION OF CHRONIC KIDNEY DISEASE STAGE III' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 20:35:23
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:36:13
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'HYPERKALEMIA RELATED TO ACUTE EXACERBATION OF CHRONIC KIDNEY DISEASE STAGE III'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'l'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'g (g)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once (ONCE)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Intravenous (INTRAVENOUS)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '26 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '26 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User entered empty.	System	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User entered empty.	System	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:00:41
User entered empty.	System	22 Oct 2020 18:17:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE WATER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:50:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:50:36
Data point term sent to Coder	System	22 Oct 2020 18:20:05
User entered 'Dextrose 50% in water'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'hyperkalemia related to acute exacerbation of chronic kidney disease stage III'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User closed query 'Per DM CLR: Please provide dosage in ML and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 08:17:43
Query 'Per DM CLR: Please provide dosage in ML and update as appropriate. ' answered with 'updated' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 20:39:04
DataPoint Un-verified.	Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 20:38:51
User entered '50' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 20:38:51
User opened query 'Per DM CLR: Please provide dosage in ML and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:41:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '25'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Un-verified.	(b) (4)	
	Sarah Bechnak (b) (4)	08 Dec 2020 20:38:51
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	08 Dec 2020 20:38:51
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'g (g)'	Sarah Bechnak (b) (4)	22 Oct 2020 18:19:07
	(b) (4)	

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once (ONCE)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Intravenous (INTRAVENOUS)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '26 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '26 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User entered empty.	System	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User entered empty.	System	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:18:48
User entered empty.	System	22 Oct 2020 18:19:07

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:41:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:41:44
Data point term sent to Coder	System	22 Oct 2020 18:28:22
User entered 'Regular insulin'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'hyperkalemia related to acute exacerbation of chronic kidney disease stage III'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '10'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	22 Oct 2020 18:27:51
User entered 'units' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:51
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	22 Oct 2020 18:27:38
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'twice daily (BID)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Intravenous (INTRAVENOUS)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '26 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '26 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User entered '2'	System	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User entered '1'	System	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:42
User entered '804 (804)'	System	22 Oct 2020 18:27:38

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:01:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:01:26
Data point term sent to Coder	System	22 Oct 2020 18:30:30
User entered 'Lidocaine topical patch 5%'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Gout exacerbation in right knee'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'l'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'patch'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Topical (TOPICAL)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '26 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '30 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User entered '1'	System	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User entered '1'	System	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:38
User entered '804 (804)'	System	22 Oct 2020 18:29:40

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:53:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:53:34
Data point term sent to Coder	System	22 Oct 2020 18:32:52
User entered 'Prednisone'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Gout exacerbation in right knee'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '40'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '26 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '02 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User entered '1'	System	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User entered '1'	System	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:43:01
User entered '804 (804)'	System	22 Oct 2020 18:32:17

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:17:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:17:29
Data point term sent to Coder	System	22 Oct 2020 18:35:35
User entered 'Sodium Bicarbonate'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'acidosis related to acute exacerbation of chronic kidney disease stage III'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '650'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	22 Oct 2020 18:39:27
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	22 Oct 2020 18:39:27
User entered 'three times daily (TID)' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:39:27
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	22 Oct 2020 18:35:13
User entered 'once (ONCE)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Intravenous (INTRAVENOUS)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '29 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '30 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User entered '3'	System	22 Oct 2020 18:39:27
User entered empty.	System	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User entered '1'	System	22 Oct 2020 18:39:27
User entered empty.	System	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:16
User entered '804 (804)'	System	22 Oct 2020 18:39:27
User entered empty.	System	22 Oct 2020 18:35:13

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSPHATEMIA, PRODUCT: SODIUM POLYSTYRENE SULFONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:15:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:15:23
Data point term sent to Coder	System	22 Oct 2020 18:41:55
User entered 'SODIUM POLYSTYRENE SULFONATE (KAYEXELATE)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'HYPERKALEMIA RELATED TO ACUTE EXACERBATION OF CHRONIC KIDNEY DISEASE STAGE III'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '30'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'g (g)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'twice daily (BID)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '27 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '27 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User entered '2'	System	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User entered '1'	System	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:56:27
User entered '804 (804)'	System	22 Oct 2020 18:41:03

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA VIRUS VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 18:45:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 18:45:39
Data point term sent to Coder	System	22 Oct 2020 18:45:02
User entered 'Influenza virus vaccine'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'influenza prophylaxis'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0.5'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'mL (mL)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'once (ONCE)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'Intramuscular (INTRAMUSCULAR)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '30 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered '30 Sep 2020'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:23:54
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User entered empty.	System	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User entered empty.	System	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:59:03
User entered empty.	System	22 Oct 2020 18:44:45

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:10:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:10:58
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:26:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:38:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:38:04
Data point term sent to Coder	System	08 Dec 2020 20:41:27
Coding entries removed.	Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 20:40:48
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 03:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 03:42:54
Data point term sent to Coder	System	11 Nov 2020 15:09:22
User entered 'Iron'	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:51
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 08:22:58
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 20:40:55
DataPoint Un-verified.	Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 20:40:48
User entered 'ACUTE DECOMPENSATED HEART FAILURE' reason for change: Per Query Resolution	Sarah Bechnak (b) (4) (b) (4)	08 Dec 2020 20:40:48
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 07:20:14
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:56
User entered 'Shortness of breath due to acute decompensated heart failure'	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:01
User entered '400'	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:04
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:06
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:07
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:14
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:15
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:17
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:20
User entered '09 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:22
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:25
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:27
User entered '09 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User closed query 'Please confirm if this was a solicited event. Per the CM log, this was not a solicited event.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 04:23:26
Query 'Please confirm if this was a solicited event. Per the CM log, this was not a solicited event.' answered with 'reviewed and updated' (Site from CRA).	Sarah Bechnak (b) (4) (b) (4)	02 Dec 2020 20:52:06
User entered 'No (N)' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	02 Dec 2020 20:51:56
User opened query 'Please confirm if this was a solicited event. Per the CM log, this was not a solicited event.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 18:22:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User entered empty.	System	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User entered empty.	System	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:55:02
User entered empty.	System	11 Nov 2020 15:09:09

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:22:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:26:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:26:41
Data point term sent to Coder	System	12 Nov 2020 18:36:43
User entered 'furosemide'	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:22:51
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:00
User entered 'Shortness of breath due to acute decompensated heart failure'	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:03
User entered '40'	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:06
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:07
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:10
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:12
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:13
User entered 'Intravenous (INTRAVENOUS)'	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:16
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:29
User entered '09 Nov 2020'	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:32
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:34
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:36
User entered '10 Nov 2020'	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:40
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User entered '1'	System	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User entered '1'	System	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:36:20
User entered '804 (804)'	System	12 Nov 2020 18:36:04

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS, CONCENTRATED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:40:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:40:47
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:26:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 17:44:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 17:44:39
Data point term sent to Coder	System	22 Dec 2020 14:51:27
User entered 'Packed red blood cells'	Sarah Bechnak (b) (4) (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'SAE: Exacerbation of anemia'	(b) (4) Sarah Bechnak (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'I'	(b) (4) Sarah Bechnak (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User closed query 'Per CDM: Dose unit is recorded as Other-UNIT; However "IU" is one of the available pre defined equivalent option under Dose Unit drop down. Please change 'Other' to 'IU' for Dose Unit and remove entry from 'If dose unit is Other, specify' field. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 12:50:00
Query 'Per CDM: Dose unit is recorded as Other-UNIT; However "IU" is one of the available pre defined equivalent option under Dose Unit drop down. Please change 'Other' to 'IU' for Dose Unit and remove entry from 'If dose unit is Other, specify' field. Thank you.' answered with 'IU: international unit is not the unit dose to be used. IU is different than unit. Unit is the correct dose unit.' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	31 Dec 2020 18:09:40
User opened query 'Per CDM: Dose unit is recorded as Other-UNIT; However "IU" is one of the available pre defined equivalent option under Dose Unit drop down. Please change 'Other' to 'IU' for Dose Unit and remove entry from 'If dose unit is Other, specify' field. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 07:36:52
User entered 'Other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'unit'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'once (ONCE)'	(b) (4) Sarah Bechnak (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Sarah Bechnak (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '22 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '22 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User entered empty.	System	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User entered empty.	System	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:54
User entered empty.	System	22 Dec 2020 14:51:00

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PROTONIX [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 13:02:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 13:02:42
Data point term sent to Coder Coding entries removed.	System Sarah Bechnak (b) (4)	19 Feb 2021 17:04:42 19 Feb 2021 17:04:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PROTONIX [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 00:24:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 00:24:59
Data point term sent to Coder	System	26 Jan 2021 18:58:11
User entered 'omeprazole (protonix)'	Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
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. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 10:18:09
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Medication given as a treatment for initial suspicion of GI bleed.' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 17:04:40
User entered 'AE#3: exacerbation of anemia' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	19 Feb 2021 17:04:36
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. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 01:58:10
User entered 'AE#3'	Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:57:46

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'UNK'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:57:46

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'mg (mg)'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'once (ONCE)'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'Intravenous (INTRAVENOUS)'	Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '21 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '0'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '21 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'No (N)'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:57:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User entered empty.	System	26 Jan 2021 18:57:46

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User entered empty.	System	26 Jan 2021 18:57:46

US3482145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:20:18
User entered empty.	System	26 Jan 2021 18:57:46

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:47:49

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	21 Oct 2020 19:47:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	21 Oct 2020 18:51:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	21 Oct 2020 18:51:10
User entered 'No (N)'	(b) (4)	
	Sarah Bechnak (b) (4)	26 Aug 2020 18:05:51
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:47:49

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
User entered '11 Sep 2020'	Sarah Bechnak (b) (4)	21 Oct 2020 19:54:12
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:47:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'ECHOCARDIOGROPHAY'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	21 Oct 2020 19:54:12

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	21 Oct 2020 19:54:12

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:47:49

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
User entered empty.	Sarah Bechnak (b) (4)	21 Oct 2020 19:54:12
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:47:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '02 Sep 2020'	(b) (4) Sarah Bechnak (b) (4)	10 Dec 2020 17:05:47

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:47:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'BLOOD CULTURE'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:05:47

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4)	
	System	10 Dec 2020 17:05:57
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	10 Dec 2020 17:05:47
User entered 'Adverse Event (AE)'	Sarah Bechnak (b) (4)	10 Dec 2020 17:05:47
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:47:49

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	10 Dec 2020 17:05:57
User entered 'SEPSIS DUE TO BETA HEMOLYTIC STREPTOCOCCUS BACTEREMIA'	(b) (4)	
	Sarah Bechnak (b) (4)	10 Dec 2020 17:05:47
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:47:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '02 Sep 2020'	(b) (4) Sarah Bechnak (b) (4)	10 Dec 2020 17:06:29

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:47:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'URINE CULTURE'	(b) (4) Sarah Bechnak (b) (4)	10 Dec 2020 17:06:29

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'Adverse Event (AE)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:06:29

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:47:49

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	10 Dec 2020 17:06:29

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:47:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '02 Sep 2020'	(b) (4) Sarah Bechnak (b) (4)	10 Dec 2020 17:06:47

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:47:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'BLOOD WORKUP'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:06:47

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'Adverse Event (AE)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	10 Dec 2020 17:06:47

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:47:49

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	10 Dec 2020 17:06:47

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:47:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:59
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '23 Oct 2020'	(b) (4)	
	Sarah Bechnak (b) (4)	26 Jan 2021 18:24:59
	(b) (4)	
DataPoint activated with code reason code Data required.	Sarah Bechnak (b) (4)	26 Jan 2021 18:20:20
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sarah Bechnak (b) (4)	22 Dec 2020 14:41:34
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:47:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:59
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'diagnostic colonoscopy'	(b) (4)	
	Sarah Bechnak (b) (4)	26 Jan 2021 18:24:59
	(b) (4)	
DataPoint activated with code reason code Data required.	Sarah Bechnak (b) (4)	26 Jan 2021 18:20:20
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sarah Bechnak (b) (4)	22 Dec 2020 14:41:34
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:59
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'Adverse Event (AE)'	(b) (4)	
	Sarah Bechnak (b) (4)	26 Jan 2021 18:24:59
	(b) (4)	
DataPoint activated with code reason code Data required.	Sarah Bechnak (b) (4)	26 Jan 2021 18:20:20
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sarah Bechnak (b) (4)	22 Dec 2020 14:41:34
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:47:49

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:43:59
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	26 Jan 2021 18:24:59
	(b) (4)	
DataPoint activated with code reason code Data required.	Sarah Bechnak (b) (4)	26 Jan 2021 18:20:20
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sarah Bechnak (b) (4)	22 Dec 2020 14:41:34
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:47:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '21 Oct 2020'	(b) (4)	
	Sarah Bechnak (b) (4)	26 Jan 2021 18:30:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Sarah Bechnak (b) (4)	26 Jan 2021 18:30:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sarah Bechnak (b) (4)	22 Dec 2020 14:41:24
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:47:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'blood workup'	(b) (4)	
	Sarah Bechnak (b) (4)	26 Jan 2021 18:30:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Sarah Bechnak (b) (4)	26 Jan 2021 18:30:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sarah Bechnak (b) (4)	22 Dec 2020 14:41:24
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'Adverse Event (AE)'	(b) (4)	
	Sarah Bechnak (b) (4)	26 Jan 2021 18:30:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Sarah Bechnak (b) (4)	26 Jan 2021 18:30:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sarah Bechnak (b) (4)	22 Dec 2020 14:41:24
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:47:49

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty.	(b) (4)	
	Sarah Bechnak (b) (4)	26 Jan 2021 18:30:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Sarah Bechnak (b) (4)	26 Jan 2021 18:30:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sarah Bechnak (b) (4)	22 Dec 2020 14:41:24
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:47:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '22 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:30:55

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:47:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'blood workup'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:30:55

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'Adverse Event (AE)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:30:55

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:47:49

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:30:55

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:47:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '21 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:34:08

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:47:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'chest x-ray'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:34:08

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'Adverse Event (AE)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:34:08

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:47:49

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:34:08

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:47:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '21 Oct 2020'	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:47:50

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:47:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'EKG'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:47:50

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:47:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'Adverse Event (AE)'	(b) (4) Sarah Bechnak (b) (4) (b) (4)	26 Jan 2021 18:47:50

US3482145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:47:49

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:44:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered empty.	(b) (4) Sarah Bechnak (b) (4)	26 Jan 2021 18:47:50

US3482145

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:47:49

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:14:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered '23 Sep 2020'	(b) (4) Sarah Bechnak (b) (4)	09 Nov 2020 21:06:42
	(b) (4)	

US3482145

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:47:49

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:14:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as Other - Doesn't meet Inclusion criteria. However reason for study treatment not given in Exposure form is recorded as Physician withheld dose due to AE. Please select the appropriate pre-defined option available instead of Other. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 11:19:40
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as Other - Doesn't meet Inclusion criteria. However reason for study treatment not given in Exposure form is recorded as Physician withheld dose due to AE. Please select the appropriate pre-defined option available instead of Other. Thank you.' answered with 'Reviewed and updated exposure in visit 2' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	17 Nov 2020 14:19:28
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as Other - Doesn't meet Inclusion criteria. However reason for study treatment not given in Exposure form is recorded as Physician withheld dose due to AE. Please select the appropriate pre-defined option available instead of Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 10:55:48
User entered 'Other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	09 Nov 2020 21:06:42

US3482145

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:14:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:13:26
User entered 'does not meet inclusion criteria number 7'	(b) (4) Sarah Bechnak (b) (4)	09 Nov 2020 21:06:42

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
User entered '12/Sep/2020 17:11'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'I'	(b) (4), (b) (6)	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
User entered '15/Sep/2020 10:28'	System	15 Sep 2020 14:28:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 14:28:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
User entered '23/Sep/2020 10:54'	System	23 Sep 2020 14:54:05

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 17:26:30
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 14:54:05

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
User entered '23/Sep/2020 13:26'	System	23 Sep 2020 17:26:46

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:26:46

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
User entered '23/Sep/2020 22:05'	System	24 Sep 2020 02:05:11

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 12:48:51
User entered 'I'	(b) (4), (b) (6)	24 Sep 2020 02:05:11

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
User entered '06/Oct/2020 12:49'	System	06 Oct 2020 12:49:12

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:48:02
User entered 'I'	(b) (4), (b) (6)	06 Oct 2020 12:49:12

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
User entered '22/Oct/2020 18:48'	System	22 Oct 2020 18:48:13

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:55:13
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 18:48:13

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
User entered '23/Oct/2020 13:46'	System	23 Oct 2020 13:46:41

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:11:54
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 13:46:41

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
User entered '29/Oct/2020 16:12'	System	29 Oct 2020 16:12:08

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:15:25
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 16:12:08

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
User entered '03/Nov/2020 16:15'	System	03 Nov 2020 16:15:55

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:48:52
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 16:15:55

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:36
User entered '10/Nov/2020 09:49'	System	10 Nov 2020 14:49:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:15:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:38:36
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 14:49:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:54:01
User entered '10/Nov/2020 11:46'	System	10 Nov 2020 16:46:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:54:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:15:43
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 16:46:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:54:01
User entered '11/Nov/2020 15:16'	System	11 Nov 2020 15:16:11

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 17:47:49

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:15:58
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:54:01
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 15:16:11

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '12/Nov/2020 15:43'	(b) (4) System	12 Nov 2020 15:43:58

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:15:58
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 15:43:58

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (16)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '25/Nov/2020 19:16'	(b) (4) System	25 Nov 2020 19:16:16

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (16)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:04:07
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 19:16:16

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'USA-US106-2020-MRNA-1273-P301000001'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:38:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:04:57
Un-reviewed for Safety.	System	24 Sep 2020 02:04:34
DataPoint Un-verified.	System	24 Sep 2020 02:04:34
User entered 'Yes (Y)'	System	24 Sep 2020 02:04:34
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'Yes (Y)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:11:37
User entered 'No (N)'	System	12 Sep 2020 21:10:38

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Easton'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
Amendment Manager: User entered 'Beshears'	System	14 Sep 2020 22:08:47

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
	(b) (4)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:01:59
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 21:09:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:28:04
User entered 'US' (non-conformant).	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	22 Dec 2020 21:04:21
User entered '15'	System	25 Nov 2020 19:16:16
User entered '14'	System	12 Nov 2020 15:43:58
User entered '13'	System	11 Nov 2020 15:16:11
User entered '12'	System	10 Nov 2020 16:46:35
User entered '11'	System	10 Nov 2020 14:49:03
User entered '10'	System	03 Nov 2020 16:15:55
User entered '9'	System	29 Oct 2020 16:12:08
User entered '8'	System	23 Oct 2020 13:46:41
User entered '7'	System	22 Oct 2020 18:48:13
User entered '6'	System	06 Oct 2020 12:49:12
User entered '5'	System	24 Sep 2020 02:05:11
User entered '4'	System	23 Sep 2020 17:26:46
User entered '3'	System	23 Sep 2020 14:54:05
User entered '2'	System	15 Sep 2020 14:28:20
User entered '1'	System	12 Sep 2020 21:11:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (17)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '22/Dec/2020 16:04'	(b) (4) System	22 Dec 2020 21:04:21

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000001

Form: Safety Report Form (17)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 21:04:28
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 21:04:21

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'USA-US106-2020-MRNA-1273-P301000004'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Yes (Y)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Yes (Y)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Easton'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Beshears'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:16:50
User entered 'US'	System	17 Nov 2020 17:20:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Jan 2021 19:25:44
User entered '3'	System	11 Dec 2020 15:36:15
User entered '2'	System	25 Nov 2020 19:17:01
User entered '1'	System	17 Nov 2020 17:20:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'USA-US106-2020-MRNA-1273-P301000004'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Yes (Y)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Yes (Y)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Easton'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Beshears'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:16:50
User entered 'US'	System	17 Nov 2020 17:20:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Jan 2021 19:25:44
User entered '3'	System	11 Dec 2020 15:36:15
User entered '2'	System	25 Nov 2020 19:17:01
User entered '1'	System	17 Nov 2020 17:20:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '17/Nov/2020 12:20'	(b) (4) System	17 Nov 2020 17:20:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:16:50
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 17:20:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'USA-US106-2020-MRNA-1273-P301000004'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Yes (Y)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Yes (Y)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Easton'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Beshears'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:16:50
User entered 'US'	System	17 Nov 2020 17:20:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Jan 2021 19:25:44
User entered '3'	System	11 Dec 2020 15:36:15
User entered '2'	System	25 Nov 2020 19:17:01
User entered '1'	System	17 Nov 2020 17:20:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '25/Nov/2020 19:16'	(b) (4) System	25 Nov 2020 19:17:01

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:35:51
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 19:17:01

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'USA-US106-2020-MRNA-1273-P301000004'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Yes (Y)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Yes (Y)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Easton'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Beshears'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:16:50
User entered 'US'	System	17 Nov 2020 17:20:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Jan 2021 19:25:44
User entered '3'	System	11 Dec 2020 15:36:15
User entered '2'	System	25 Nov 2020 19:17:01
User entered '1'	System	17 Nov 2020 17:20:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '11/Dec/2020 10:36'	(b) (4) System	11 Dec 2020 15:36:15

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:25:30
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 15:36:15

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'USA-US106-2020-MRNA-1273-P301000004'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Yes (Y)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Yes (Y)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'No (N)'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Easton'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:08
User entered 'Beshears'	System	17 Nov 2020 17:19:34

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:16:50
User entered 'US'	System	17 Nov 2020 17:20:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Jan 2021 19:25:44
User entered '3'	System	11 Dec 2020 15:36:15
User entered '2'	System	25 Nov 2020 19:17:01
User entered '1'	System	17 Nov 2020 17:20:20

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '14/Jan/2021 19:25'	(b) (4) System	14 Jan 2021 19:25:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:25:44

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'USA-US106-2020-MRNA-1273-P301000005'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Easton'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Beshears'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:49:47
User entered 'US'	System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Jan 2021 16:20:59
User entered '4'	System	11 Jan 2021 16:40:11
User entered '3'	System	23 Dec 2020 14:30:00
User entered '2'	System	11 Dec 2020 15:50:11
User entered '1'	System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'USA-US106-2020-MRNA-1273-P301000005'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Easton'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Beshears'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:49:47
User entered 'US'	System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Jan 2021 16:20:59
User entered '4'	System	11 Jan 2021 16:40:11
User entered '3'	System	23 Dec 2020 14:30:00
User entered '2'	System	11 Dec 2020 15:50:11
User entered '1'	System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '17/Nov/2020 12:21'	(b) (4) System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:49:47
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'USA-US106-2020-MRNA-1273-P301000005'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Easton'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Beshears'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:49:47
User entered 'US'	System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Jan 2021 16:20:59
User entered '4'	System	11 Jan 2021 16:40:11
User entered '3'	System	23 Dec 2020 14:30:00
User entered '2'	System	11 Dec 2020 15:50:11
User entered '1'	System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '11/Dec/2020 10:50'	(b) (4) System	11 Dec 2020 15:50:11

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 14:29:46
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 15:50:11

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'USA-US106-2020-MRNA-1273-P301000005'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Easton'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Beshears'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:49:47
User entered 'US'	System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Jan 2021 16:20:59
User entered '4'	System	11 Jan 2021 16:40:11
User entered '3'	System	23 Dec 2020 14:30:00
User entered '2'	System	11 Dec 2020 15:50:11
User entered '1'	System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '23/Dec/2020 14:29'	(b) (4) System	23 Dec 2020 14:30:00

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:39:46
User entered 'I'	(b) (4), (b) (6)	23 Dec 2020 14:30:00

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'USA-US106-2020-MRNA-1273-P301000005'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Easton'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Beshears'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:49:47
User entered 'US'	System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Jan 2021 16:20:59
User entered '4'	System	11 Jan 2021 16:40:11
User entered '3'	System	23 Dec 2020 14:30:00
User entered '2'	System	11 Dec 2020 15:50:11
User entered '1'	System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '11/Jan/2021 11:40'	(b) (4) System	11 Jan 2021 16:40:11

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:42
User entered 'I'	(b) (4), (b) (6)	11 Jan 2021 16:40:11

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'USA-US106-2020-MRNA-1273-P301000005'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'No (N)'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Easton'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:42
User entered 'Beshears'	System	17 Nov 2020 17:21:03

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:49:47
User entered 'US'	System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Jan 2021 16:20:59
User entered '4'	System	11 Jan 2021 16:40:11
User entered '3'	System	23 Dec 2020 14:30:00
User entered '2'	System	11 Dec 2020 15:50:11
User entered '1'	System	17 Nov 2020 17:21:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '27/Jan/2021 11:20'	(b) (4) System	27 Jan 2021 16:20:59

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:59

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'USA-US106-2020-MRNA-1273-P301000006'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'No (N)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'No (N)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'No (N)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'No (N)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'No (N)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'Easton'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'Beshears'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'US'	(b) (4) System	17 Nov 2020 17:23:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 17:23:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'USA-US106-2020-MRNA-1273-P301000006'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'No (N)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'No (N)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'Yes (Y)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'No (N)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'No (N)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'No (N)'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'Easton'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:42
User entered 'Beshears'	System	17 Nov 2020 17:22:35

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'US'	(b) (4) System	17 Nov 2020 17:23:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:47:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 17:23:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:47:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered '17/Nov/2020 12:23'	(b) (4) System	17 Nov 2020 17:23:52

US3482145

Folder: SAE USA-US106-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:47:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:26:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:52